



A Unified Response to Training Needs

**Something is Strange –
Let's Notify the LRN!**

December 17, 2024
12:00-1:30PM ET

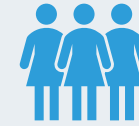
Agenda

- Introduction
 - *New and relevant OneLab™ Resources*
 - *Today's Presenters*
- Something is Strange – Let's Notify the LRN!
- Q&A: Erin Bowles, Chris Mangal, Shoolah Escott, & Alicia Branch
- Upcoming Events

Participant Rules of Engagement for the Webinar Chat

Please keep the following in mind when using the chat feature:

- **Connect with others!** React to what you're hearing, share experiences, and ask questions of your fellow participants!
- **Have a question for the presenter?** Use the Q&A function, *not* the chat.
- **Show Respect and Professionalism.** Inappropriate language, improper conduct, or any form of discrimination may result in removal from the webinar.
- **Remain on Topic.** Ensure your comments are relevant to the topic.
- **Comply with Moderators' Guidance.** If a moderator gives direction regarding chat behavior, please comply accordingly.
- **Report Issues.** Notify moderators if you experience technical difficulties or observe any disruptive behavior.



 OneLab™ is excited to **announce**

Fundamentals of Working Safely with Formaldehyde and Glutaraldehyde

This new, basic-level course introduces clinical and public health laboratory professionals to the properties of formaldehyde and glutaraldehyde and the hazards, exposure routes, health effects, control measures, and response procedures for incidents involving these chemicals.

Upon completion, you can download a certificate from OneLab REACH™ under 'My Learner Hub.'



[Register now on OneLab REACH](#)

Now Available on

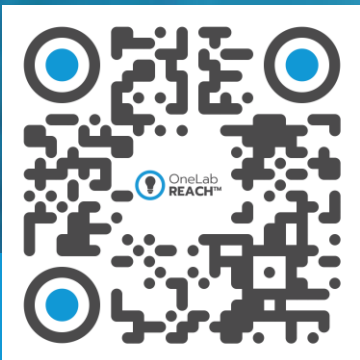


OneLab
REACH™

Diagnostic Stewardship Toolkit

Diagnostic Stewardship supports ordering the right test for the right patient at the right time to improve patient outcomes.

- OneLab™ created this toolkit to help organizations form diagnostic stewardship teams and apply guiding principles.



Visit reach.cdc.gov to download



is excited to
announce

Introduction to Clinical Laboratory Improvement Amendments (CLIA) Proficiency Testing

This basic-level eLearning course covers the fundamentals of CLIA proficiency testing (PT), explains the PT process and scoring procedures, and addresses PT referral.

- It is designed for individuals with roles associated with clinical laboratory testing and anyone interested in CLIA proficiency testing basics.
- After completing this course, learners can earn either P.A.C.E.® or CME credit.



[Register now on OneLab REACH™](#)

Disclaimer

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

Disclaimer

CDC, our planners, and our presenters wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Today's Presenter



Chris N. Mangal, MPH

*Director of Public Health Preparedness & Response
Association of Public Health Laboratories (APHL)*

Today's Presenter



Erin Bowles, BS, MLS(ASCP)

Laboratory Network Coordinator

Wisconsin State Laboratory of Hygiene

Today's Presenter



Shoolah Escott MS, MLS(ASCP)

*Biosafety, Biosecurity, and Bioterrorism
Preparedness Trainer*



A Unified Response to Training Needs

Something is Strange – Let's Notify the LRN

Chris N. Mangal, MPH

December 17, 2024

Discussion Topics



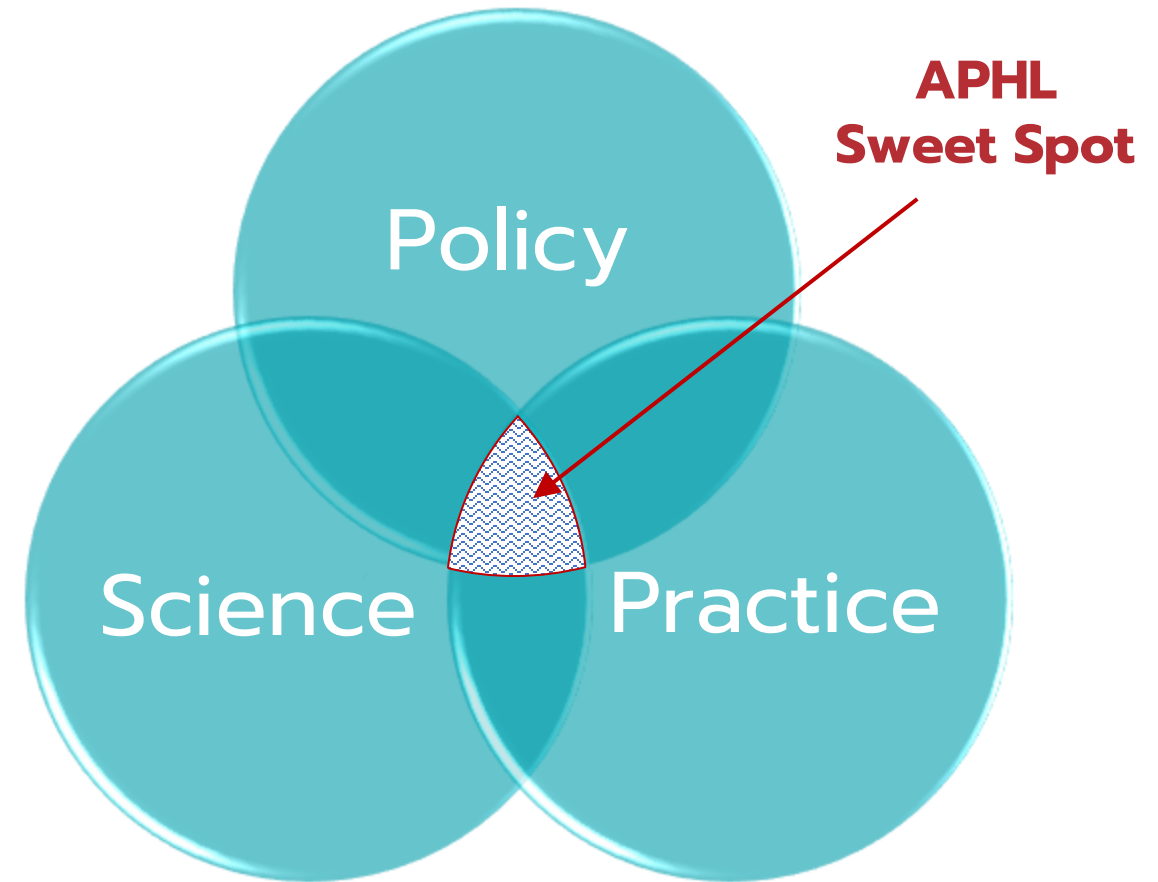
- 1 About APHL
- 2 Laboratory Response Network
- 3 Partners in Laboratory Preparedness and Response
- 4 Partner Resources for Laboratories
- 5 Contacts

Vision

A healthier world through quality laboratory systems.

Purpose

Shape national and global health outcomes by promoting the value and contribution of public health laboratories and continuously improving the public health laboratory system and practice.



What is APHL?



A 501(c)(3) non-profit organization



Has over 1,700 members from state and local public health laboratories, state environmental and agricultural laboratories and others including federal agencies and academic institutions.



Advocates at the national level for critical laboratory issues and for increased support/resources for member labs.



Provides training and best practices for public health laboratory policy and programs.

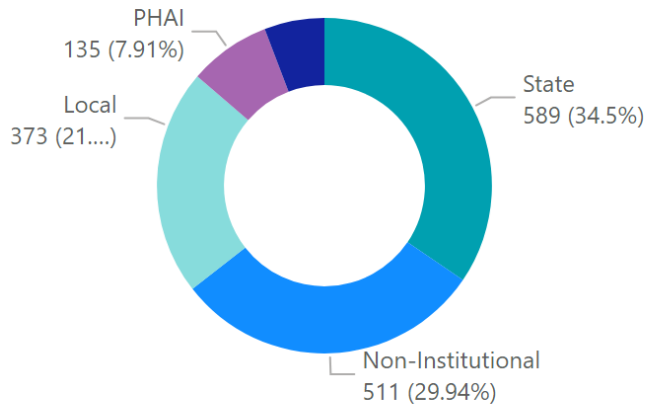
APHL Membership



Reporting Month

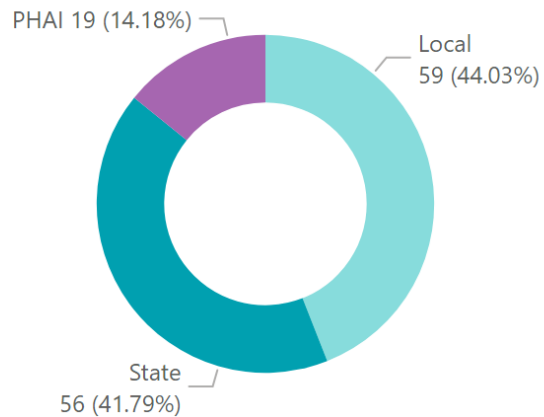
Aug-24

Member Count by Category



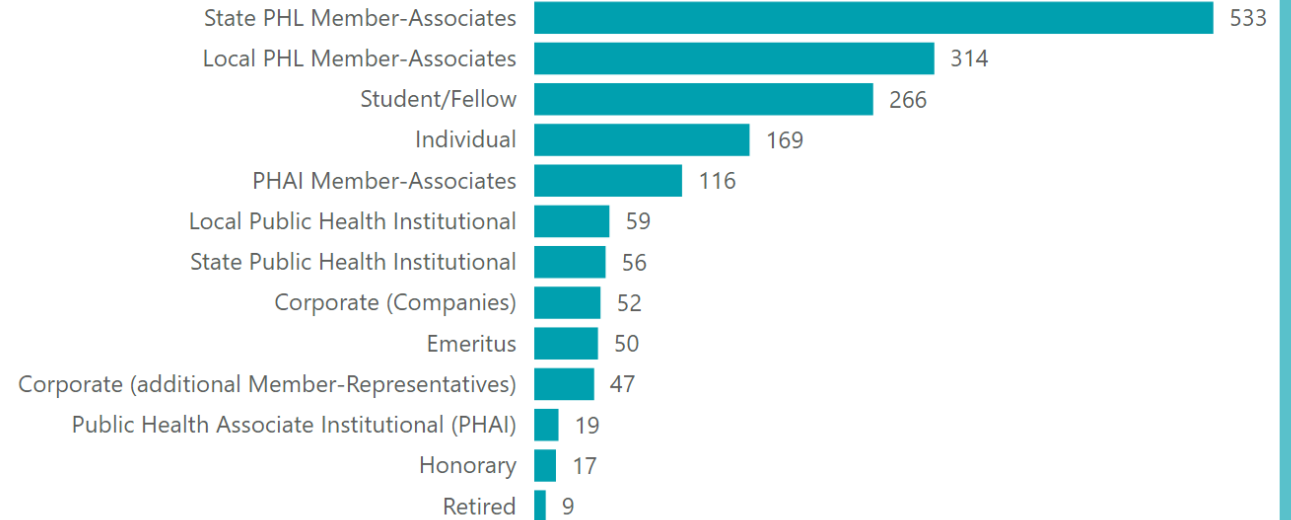
1707
Total Members

Member Laboratories



134
Total Laboratories

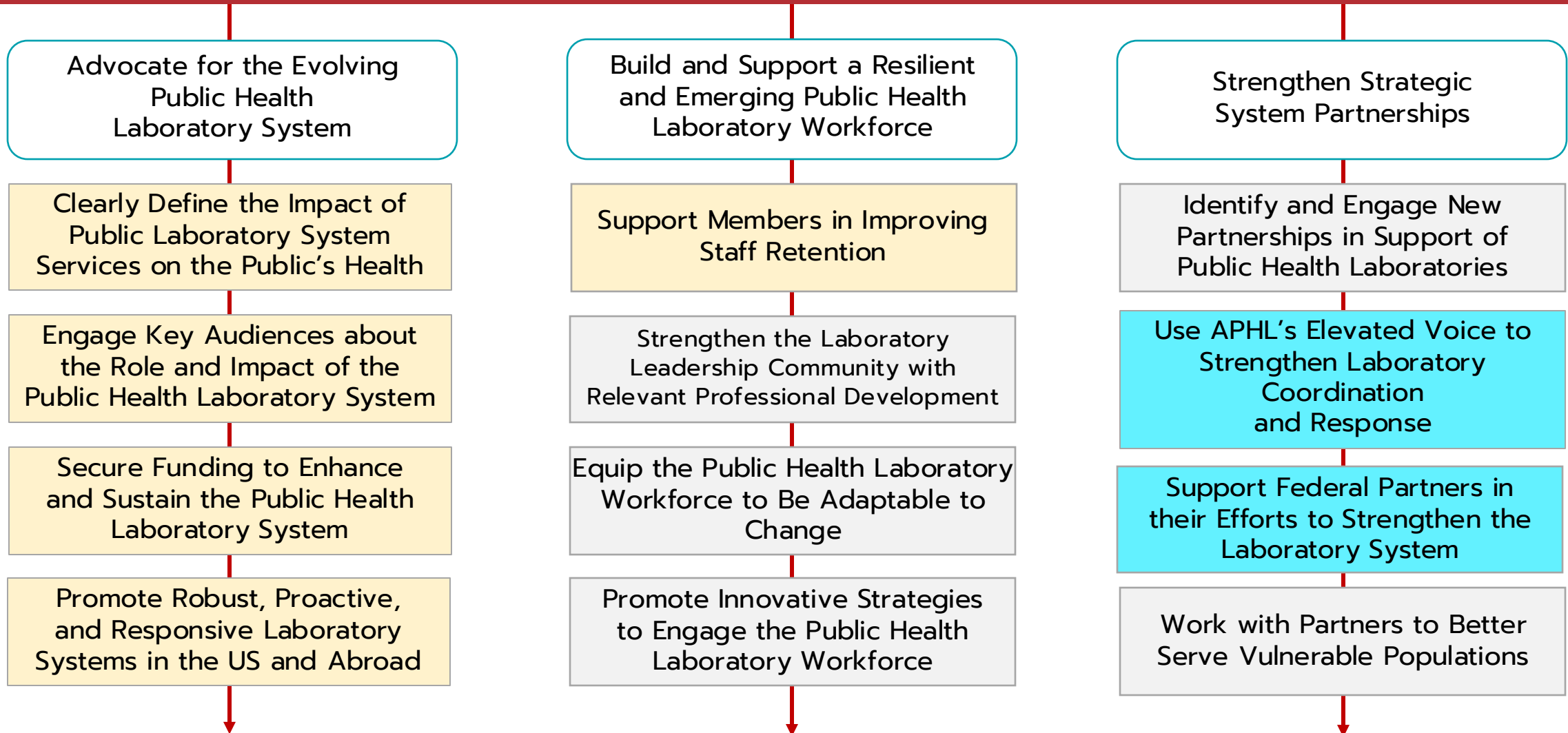
APHL Membership



Notable Membership Changes

- New Laboratory Representatives**
 - Vince Aoki - WA PHL
 - Samson Omole - ME PHL
 - Mark Pandori - Butte County PHL

Lead Public Health Laboratories through the Post-Pandemic Era



Shape the Public Health Laboratory System's Role in Advancing Diversity, Equity, Inclusion and Accessibility

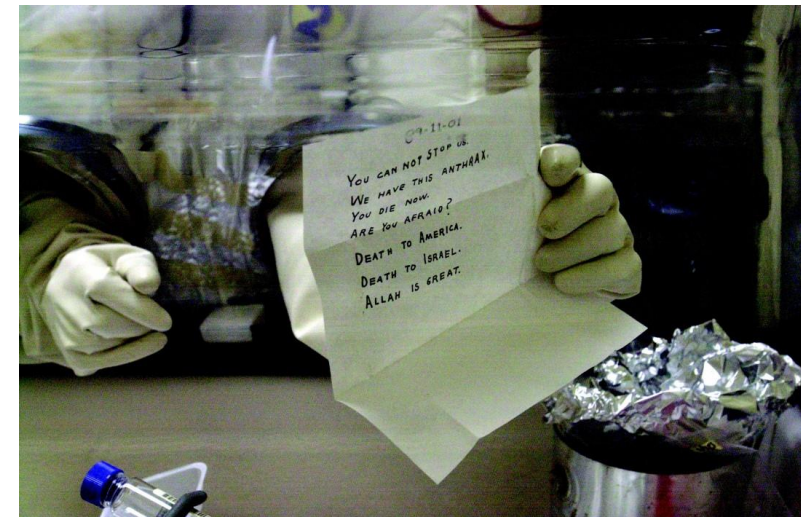
About the LRN

- Formed in 1999
- Founding Partners: APHL, CDC, FBI
- Initial focus on bioterrorism preparedness
- Has evolved to support preparedness and response to a broad range of threats

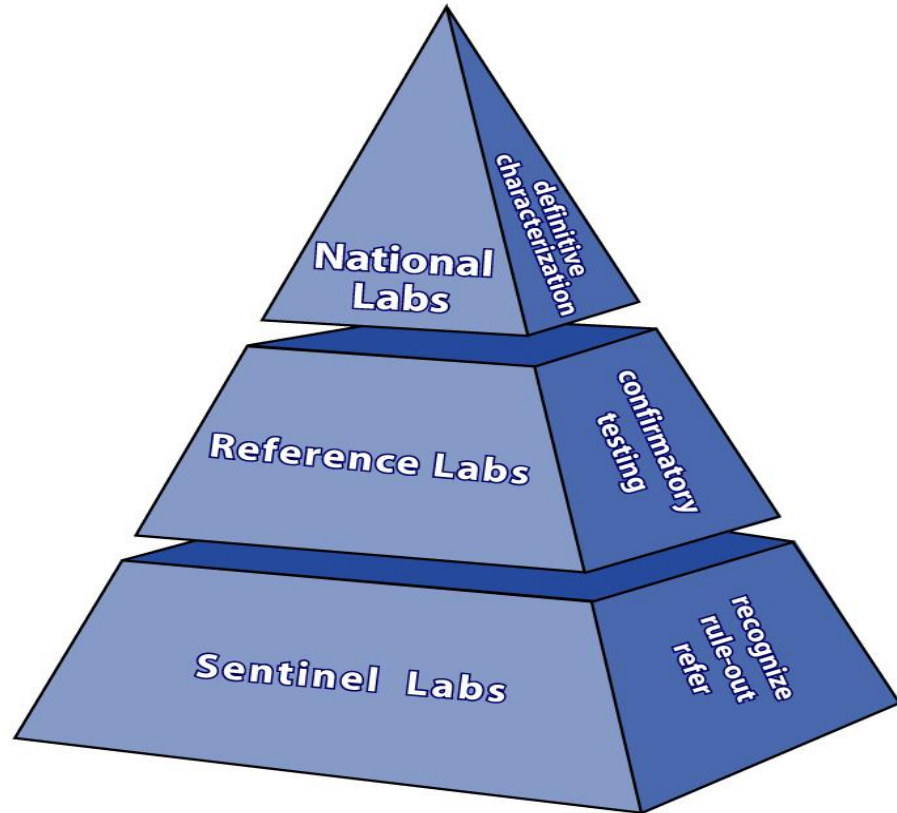
Current Mission:

To provide rapid laboratory response to biological and chemical threats to inform critical decisions about public health and safety

<https://emergency.cdc.gov/lrn/index.asp>



LRN for Biological Threats Preparedness (LRN-B)



- Standardized reagents and protocols
- Electronic data messaging and communications
- Training and technical assistance
- Quality standards, including a robust approach to biosafety and biosecurity
- Partnerships

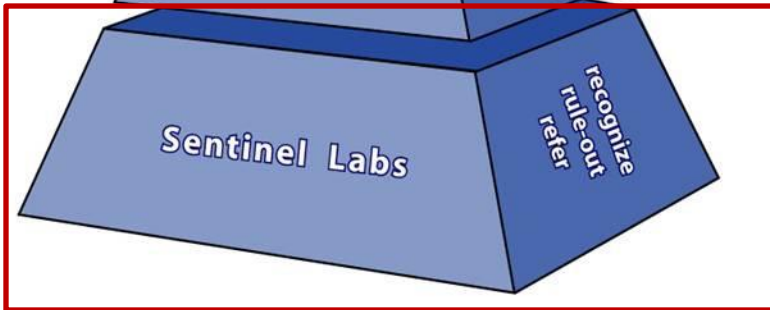
LRN-B: Sentinel Labs



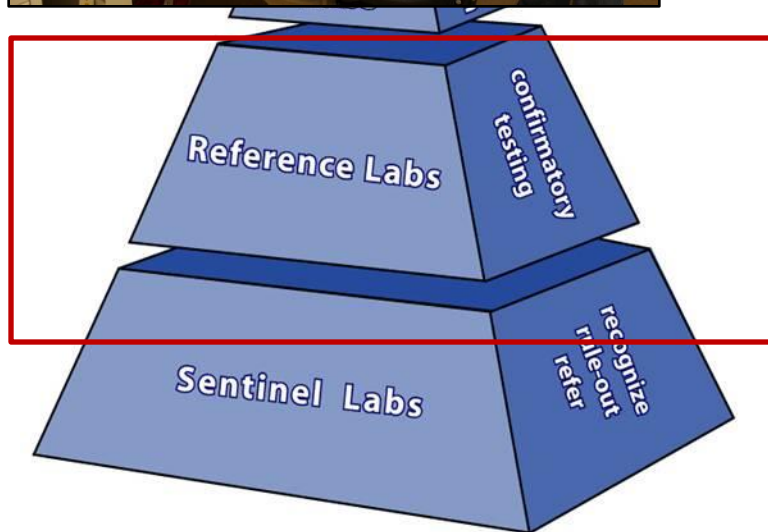
Hospitals and private clinical laboratories
Some local PHLs

Sentinel Clinical Labs

- ✓ Recognize threats and perform routine diagnostic services
- ✓ Rule-out common pathogens
- ✓ Refer specimens to reference or national laboratories for further testing, if needed



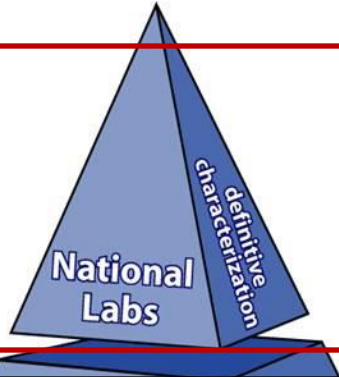
LRN-B: Reference Laboratories



Reference Laboratories:

- ✓ Public health, military, veterinary, agriculture, food, and water testing laboratories
- ✓ Receive CDC LRN-B reagents, protocols, and training
- ✓ Perform standardized tests to ensure accurate, reliable results
- ✓ Investigate and/or refer specimens and samples

LRN-B: National Labs



National Labs

- ✓ CDC
- ✓ Department of Defense

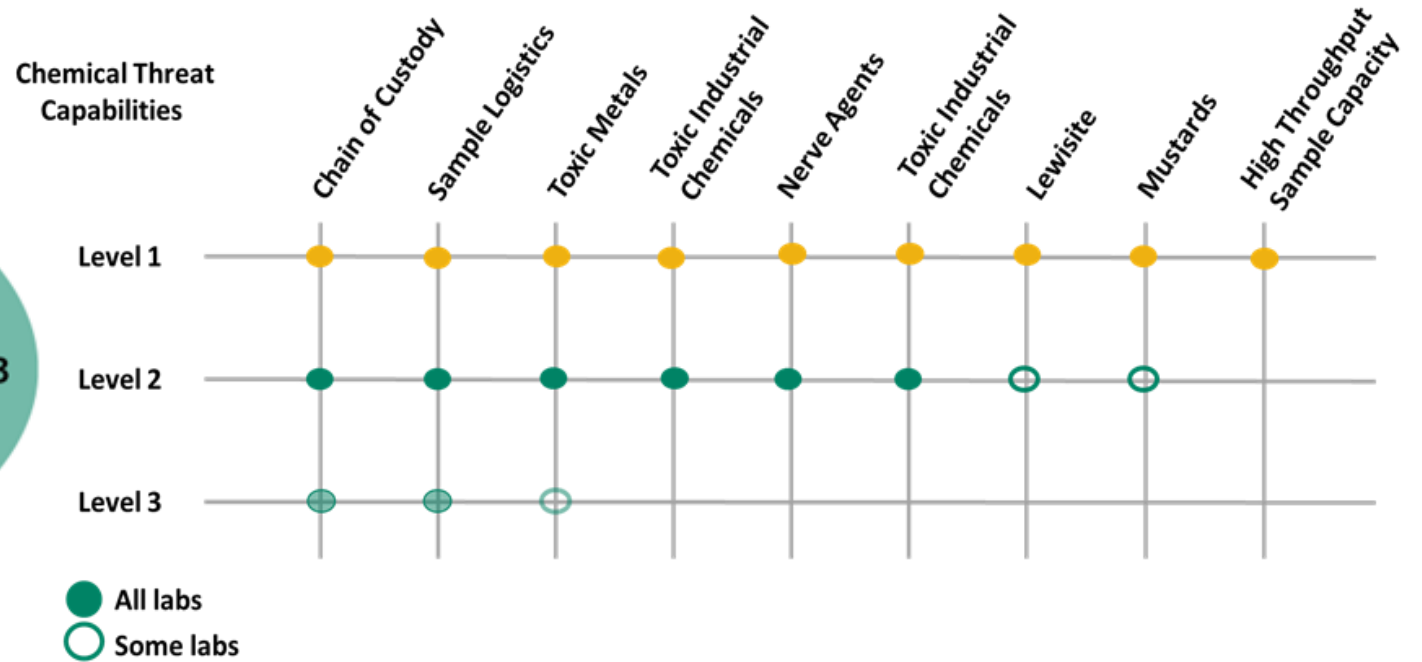
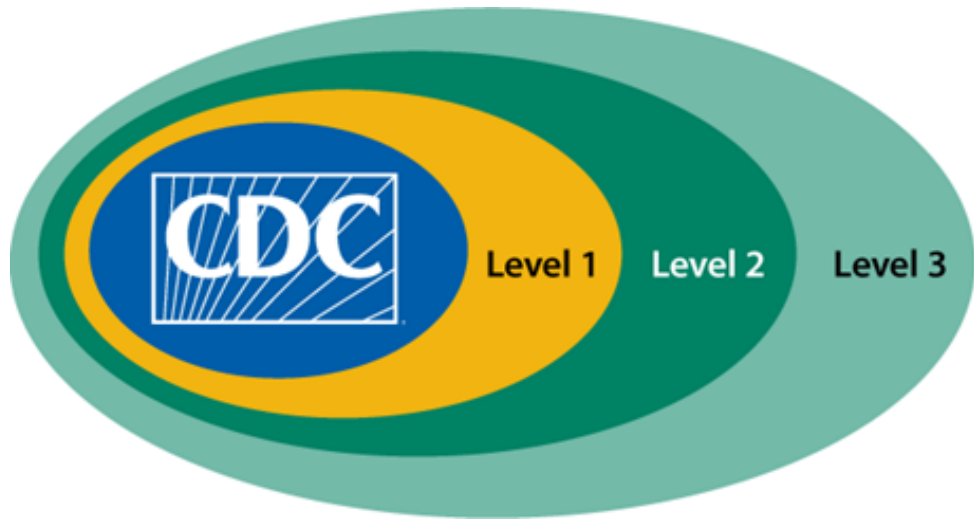
Highest technical capabilities and specialized testing

- ✓ Strain characterization
- ✓ Bioforensics

BSL-4 capabilities

Develop and deploy laboratory tests

LRN for Chemical Threats (LRN-C)



LRN for Radiological Threats

- ✓ Strong existing capabilities for radiochemistry at the state public health laboratory level
- ✓ Coordinate infrastructure and expertise
- ✓ Prioritize filling critical gaps such as workforce development



APHL's Role in the LRN

Founding member of the LRN

Recommendations to shape strategic direction of the network

Funding Advocacy and Education of Policy Makers

Public Health Emergency Preparedness (PHEP) Cooperative Agreement

Operational Support:

- Gatekeeping function to support public health laboratory access to the network
- Multicenter Evaluation Studies
- Procurement
- Training and other technical assistance
- Electronic Data Exchange
- Communications, Networking and Partnerships

Something is Strange – Let's Notify the LRN!



Something is Strange – Let's Notify the LRN!



An unusual number of ill people present suddenly with similar symptoms

Something is Strange – Let's Notify the LRN!



- What? Another Listeria?
That is 5 this week!



I had a couple of Listeria last week?



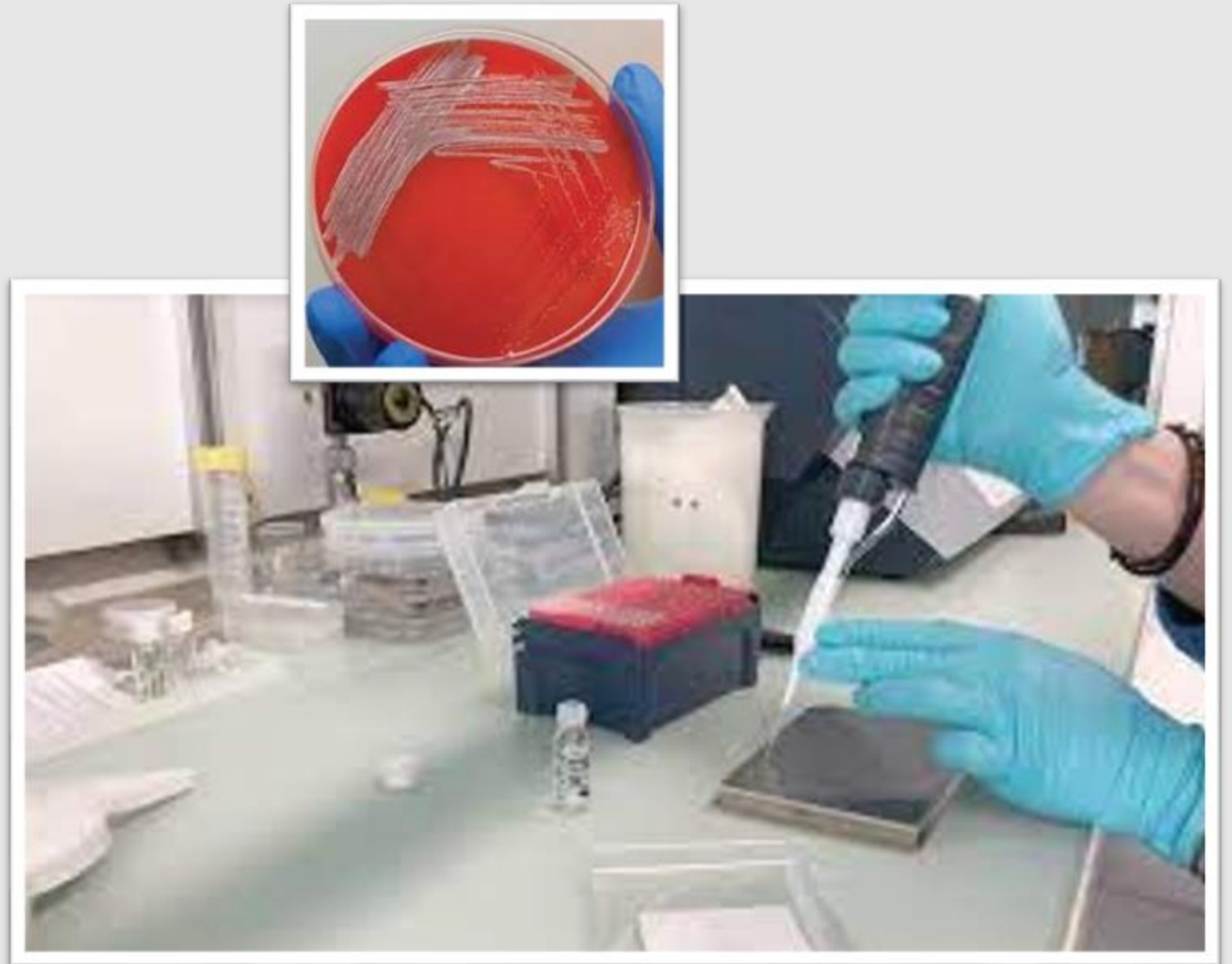
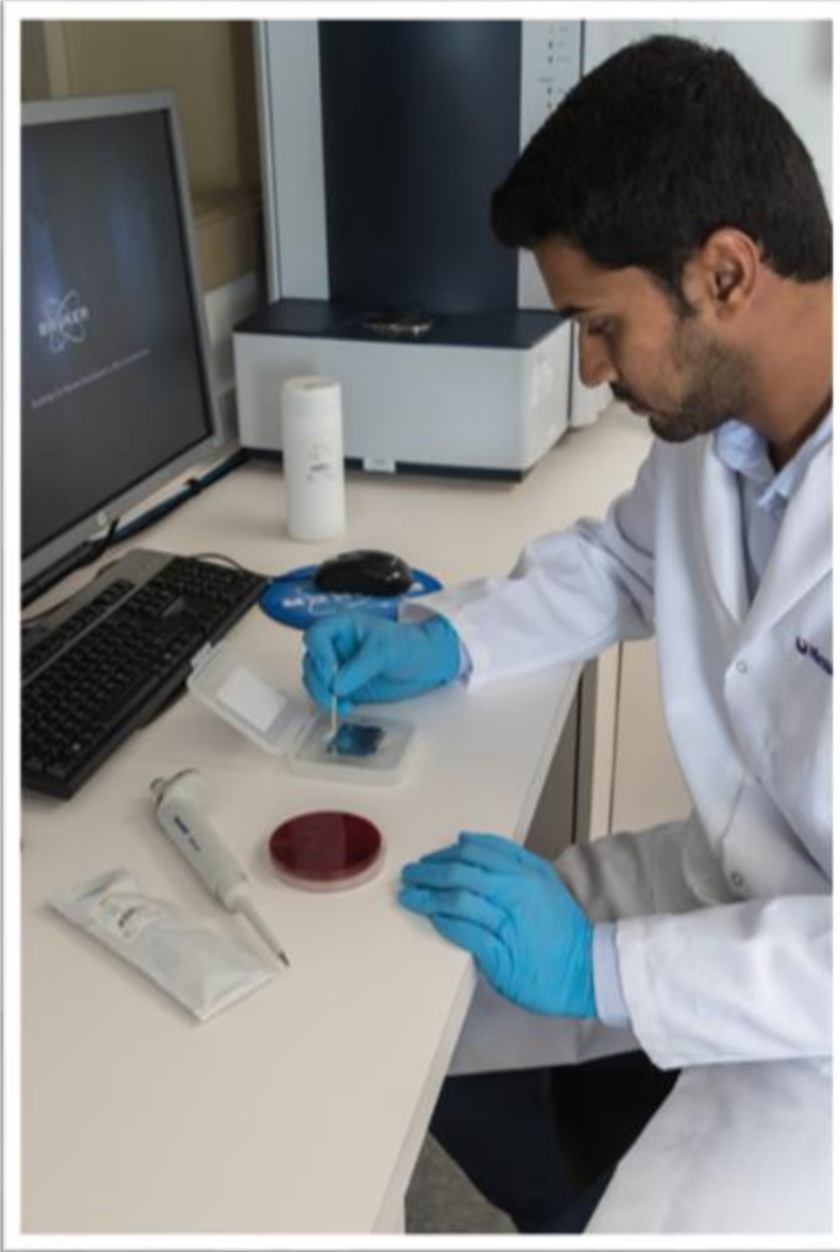
Me too!

Something is Strange – Let's Notify the LRN!



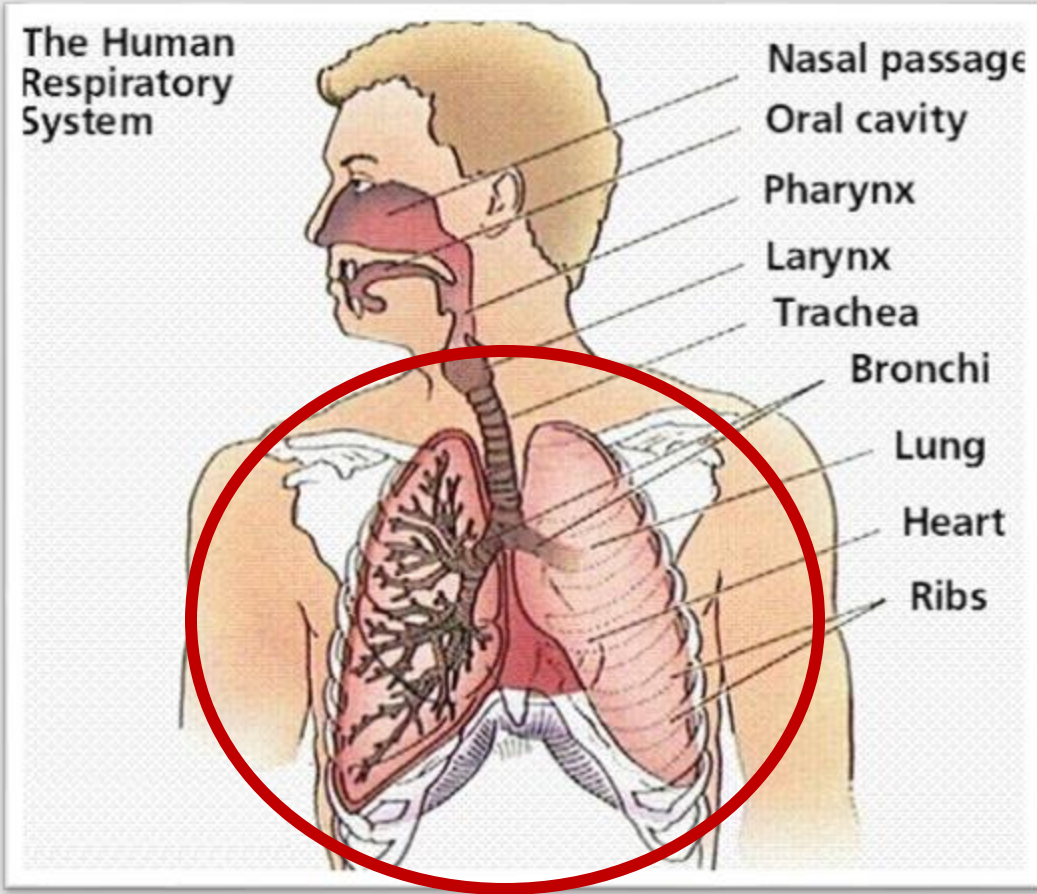
“I think we may have had an exposure!”

OK, Let Me Help! Tell Me What Happened!





Key Sources to Stop and Ask “Could This be a BT Agent?”



Lower Respiratory tissue and fluid



Blood and possibly sterile fluid

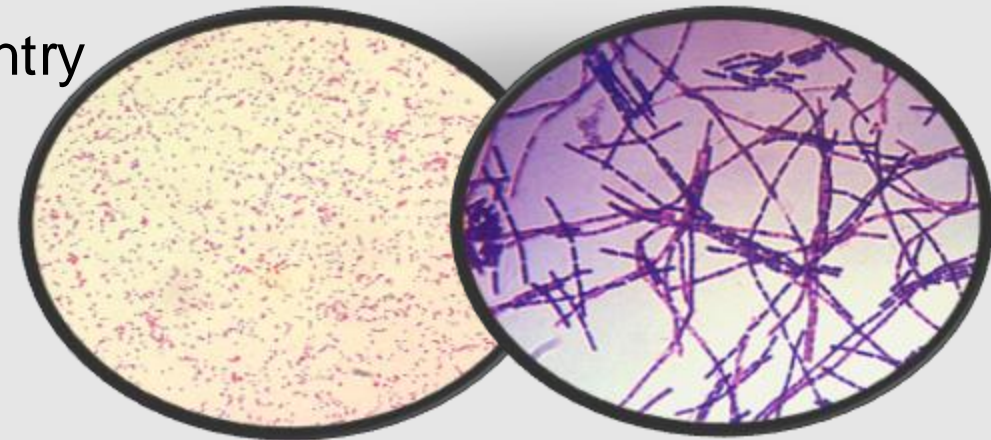


Wounds, inclusive of animal bites

Clues You Could Be Working With a BT Agent



- Blood culture takes longer than 24 hours to grow
- No growth or just a slight haze of growth at 24 hours
- Better growth on CHOC than BLD
- Gram stain shows tiny gram-variable coccobacilli
- Gram stain shows large boxcar shaped gram-positive bacilli
- Check the patient history:
 - Patient history notes travel to or has lived in a country where BT agents are endemic
 - Patient has had an insect bite or an animal bite
 - Patient works with animals
- Talk to the ordering physician



BLOOD CULTURES

Blood culture instrument signals there is a positive bottle.

Remove positive bottle to perform a Gram stain.

- Before staining, determine how long bottle has been incubating. If >24 hours, consider this may be a biotreat (BT) agent.
- Is there any patient history or a clinical note in the patient record to indicate the need to consider a possible BT agent?
- To avoid aerosols: Always make smears, allow to dry and perform any heat fixation in a certified biosafety cabinet (BSC).

Gram stain fixed slide and examine slide.

Suspect a BT agent if you see large boxcar-like Gram positive bacilli (with or without spores) or tiny GNGB.

In a BSC: Subculture positive bottles with suspected BT agent to BAP, CHOC and MAC/EMB agar plates. Tape plates shut and label: "Possible BT Agent—Open in BSC."



Always verify that BSCs are certified and functioning properly before working in them. If a BSC is unavailable, see the "Biosafety" section for alternative safety measures.

Heat or methanol fixation may not kill organisms in a dried smear. There is a slight risk of aerosol production if the slide were to drop and break when staining or reading the Gram stain slide.

WOUND AND LOWER RESPIRATORY CULTURES



Always check for any patient history or a note in the patient record to indicate a need to consider a possible BT agent.

In a BSC: Examine plates at 24 h for growth.
If no growth or only slight growth and tiny colonies, re-incubate plates.

In a BSC: Examine plates at 48 h for growth. Note:

- Time to growth?
- Colony morphology?
- Which plates have growth?
- Any hemolysis on BAP?



STOP! Do not put the organism on MALDI-TOF or other automated ID system unless all possible BT agents have been ruled-out.
See *MALDI-TOF Safety Guide*.

In a BSC: Make a smear of the colony growth for a Gram stain and allow to dry in the BSC (See note under Blood Cultures). Also perform an oxidase and tube catalase on the colony growth.

Gram stain fixed slide and examine slide. Dependent on Gram stain result, refer to APHL's "Recognize. Rule-out. Refer." bench guide and the ASM agent-specific "Sentinel Level Clinical Laboratory Guidelines" to determine further rule-out testing to perform. Always perform rule-out testing in a BSC.

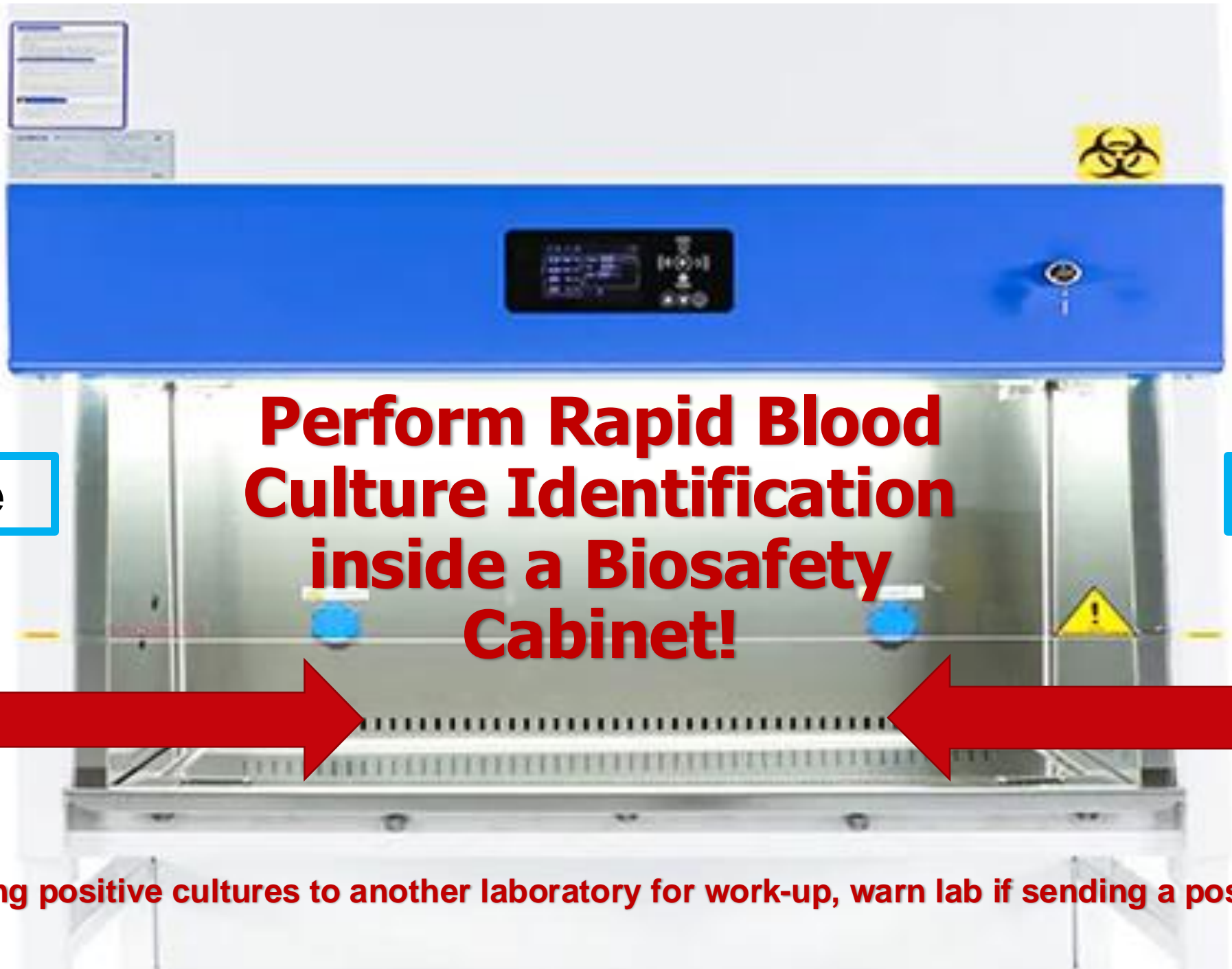
If unable to rule-out all BT agents, contact the ordering physician to discuss whether the patient's symptoms could indicate a possible BT agent.

Check if the patient has cultures from other specimens that may grow the same organism. If so, make a note in the patient electronic record on all other cultures to perform all work in a BSC due to a suspect BT agent and flag all culture media (e.g., tape/bag plates, add stickers, etc.).

Contact your LRN laboratory to notify them you have isolated a possible BT agent you are unable to rule-out and determine your next steps.

Do not use MALDI until all BT agents are ruled-out!





Verigene

BioFire

Perform Rapid Blood Culture Identification inside a Biosafety Cabinet!



Remember:

When forwarding positive cultures to another laboratory for work-up, warn lab if sending a possible BT agent!

Rule-out Testing



- Work in BSC using BSL-3 biosafety practices:
 - Safety eyewear
 - N-95 or PAPR
 - Back opening gown
- Minimal rule-out testing you must perform:
 - Catalase (tube method is safest)
 - Oxidase
- Additional rule-out testing that is helpful to perform:
 - Motility (tube method is safest)
 - Urea
 - Indole
 - B-lactamase
 - Satellite

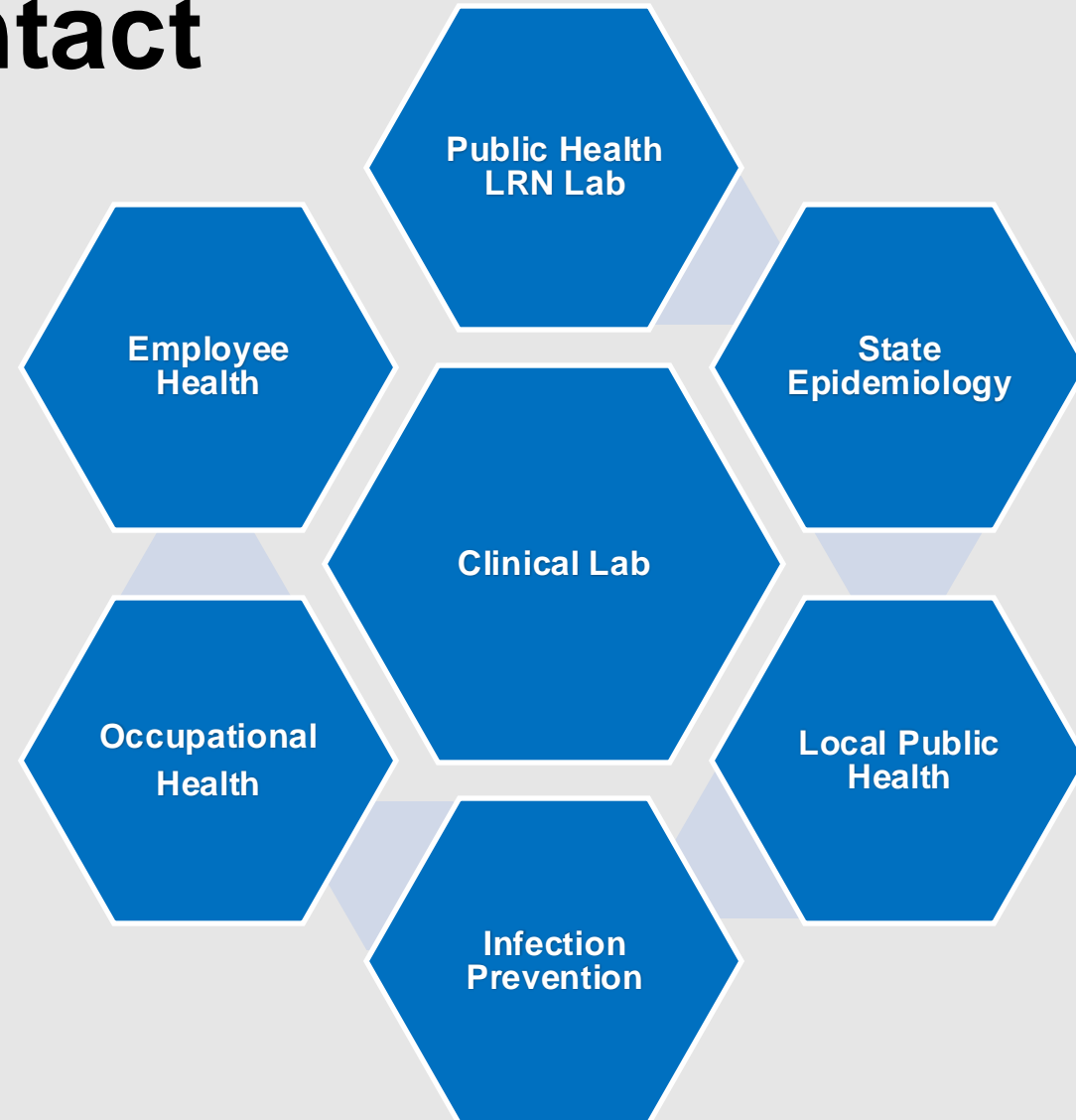


Photo courtesy of John Maniaci, UW Health



Contact Information of Partners and When to Contact

It Takes a Team of Partners



Determine Who is Responsible for W

Connect and Communicate with Partners



- How will you communicate
- Look at the big picture
- Ask questions
- Provide guidance
- Determine action plan for follow-up treatment or prophylaxis
- Discuss disposal of any remaining organism
- Determine who is responsible for what actions
- Evaluate and determine what changes need to be made to prevent further occurrences

Complete Exposure Assessment



- Determine who will do the exposure assessment
- General questions:
 - When did this occur?
 - Where was the organism worked with?
 - Who else was within 5 feet?
 - What PPE was worn?
 - What is the immune status of the individual working with the specimen and others who were within 5 feet?
- Specific Activities and Manipulations:
 - Answer yes or no to a list of common laboratory activities that are performed on specimens
- Based on answers determine whether there was an exposure and what is the level of risk.
- Determine what post-exposure follow up steps will be taken

Exposure Assessment and Monitoring Tool



CLINICAL LABORATORY BIOLOGICAL EXPOSURE EVALUATION TOOL

Potential Exposure Event Summary

Date of Potential Exposure: _____ Exposure Location(s): _____

Multiple people exposed? No Yes. Complete this form for each person to determine individual exposure risk.

Name/Identifier of Person Potentially Exposed: _____

Individual's Predispositions: Pregnant Immunocompromised Other: _____

Interactions with Organism

Individual worked with organism: Within BSC Outside BSC Did not work directly with organism

Individual did not work with organism, but was: Within five feet More than five feet

Individual wore: Gloves Lab coat/gown Safety glasses Other: _____

Individual performed the following activities or types of manipulation with organism:

- | | | |
|--|--|--|
| <input type="checkbox"/> Removed caps or swabs from culture containers, opened lyophilized cultures or cryotubes | <input type="checkbox"/> Flamed a loop | <input type="checkbox"/> Examined or manipulated |
| <input type="checkbox"/> Manipulated needles, syringes or sharps | <input type="checkbox"/> Wet preps | <input type="checkbox"/> Smear |
| | <input type="checkbox"/> Rapid antigen testing | <input type="checkbox"/> Cat |
| | <input type="checkbox"/> Blood culture bottle | <input type="checkbox"/> Other: _____ |

What work was done by whom, where and what PPE was worn? Who else was present and how close were they?

Exposure Event Follow-up

Treatment and Monitoring

Post Exposure Prophylaxis (PEP): Will begin PEP Declined PEP N/A

Serological Monitoring: Will begin serological monitoring Declined N/A

Fever Watch: Yes No N/A

Other Notes:

Corrective Actions and Mitigations

Use the risk assessment determinations above to evaluate the overall risk of exposure according to the likelihood of occurrence and severity of consequences.

What treatment is needed and who will be monitoring the treatment?





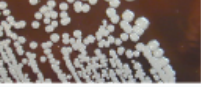
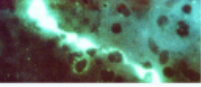






Exposure Monitoring Guide



PHPR Clinical Laboratory Biological Exposure Monitoring Guide.pdf (aphl.org)

CLINICAL LABORATORY BIOLOGICAL EXPOSURE MONITORING GUIDE



Disease (Organism/Agent)	Notes	Exposure Risks and Routes of Transmission in the Laboratory Setting ^a	Incubation Period	Symptoms (Will depend on route of transmission)
 Anthrax, Woolsorter's disease (<i>Bacillus anthracis</i>)	1, 5*, 8, 14	Direct and indirect contact of broken skin with cultures and contaminated laboratory surfaces, accidental parenteral inoculation, exposure to infectious aerosols. LD50 is 2,500-55,000 for spores and will depend on the route of exposure. < 10 spores necessary for cutaneous anthrax infection.	Typically 1-6 days, with a range up to 60 days	Cutaneous: painless sore with black eschar. Inhalational: Fever and chills, chest discomfort, body aches. Gastrointestinal: Fever, chills, swelling of neck and neck glands, sore throat, painful swallowing, stomach pain, fainting, abdominal swelling. Injection anthrax: Fever, chills, blisters or bumps that may itch, painless skin sore with black eschar, swelling around sore.
 Blastomycosis (<i>Blastomyces dermatitidis</i>)	3, 14	Accidental parenteral inoculation with infected tissues or cultures of yeast form. Pulmonary infections from inhalation of conidia from mold-form cultures.	3 weeks - 3 months	Flu like symptoms, fever, cough, night sweats, myalgia (muscle pain) and arthralgia (joint pain), weight loss and anorexia, chest pain, fatigue.
 Brucellosis, Undulant fever, Malta fever, Mediterranean fever (<i>Brucella abortus, B. suis, B. melitensis</i>)	1, 5, 14	<i>Brucella spp.</i> have a very low infectious dose and are easily aerosolized. Ingestion, inhalation, accidental parenteral inoculation or contact with broken skin or mucosa. Direct exposure to samples or cultures (outside containment). ID is 10-100 organisms by aerosol or subcutaneous exposure.	5 days - 5 months	Initial symptoms: fever, sweats, malaise, anorexia, headache, pain in muscles, joint, and/or back, fatigue. Chronic symptoms: recurrent fevers, arthritis, swelling of the testicle and scrotum area, swelling of the heart (endocarditis), neurologic symptoms (in up to 5% of all cases), chronic fatigue, depression, swelling of the liver and/or spleen.
 Glanders (<i>Burkholderia mallei</i>)	1, 5*, 14	Ingestion, inhalation, accidental parenteral inoculation, and contact with broken skin or mucosa with cultures and infected tissues, purulent drainage, blood and sputum. There is increased risk for individuals with diabetes.	1-14 days	Fever with chills and sweating, muscle aches, chest pain, muscle tightness, headache, nasal discharge, light sensitivity (sometimes with excessive tearing of the eyes), ulceration at the site of localized infection, lymphadenopathy, abscess formation.
 Meliodosis, Whitmore's disease (<i>Burkholderia pseudomallei</i>)	1, 5*, 14	Ingestion, inhalation, inoculation, and direct contact via skin abrasions and mucous membranes.	1 day - years	Localized: Localized pain or swelling, fever, ulceration, abscess. Pulmonary: Cough, chest pain, high fever, headache, anorexia. Bloodstream: Fever, headache, respiratory distress, abdominal discomfort, joint pain, disorientation. Disseminated: Fever, weight loss, stomach or chest pain, muscle or joint pain, headache, seizures.
 Psittacosis (<i>Chlamydia psittaci</i>)	1, 14	Infectious aerosols in the handling, care, or necropsy of naturally or experimentally infected birds, mice and eggs.	5-14 days	Abrupt onset of fever and chills, headache, muscle aches, nonproductive cough, splenomegaly, rash.
 Botulism (<i>Clostridium botulinum</i> toxin)	1, 5*, 13	Exposure to toxin, and especially associated with activities that have high potential for aerosol or droplet formation. 0.7-0.9 µg of inhaled aerosolized toxin is likely enough to kill a 70 kg / 150 lb person.	6 hours - 10 days	Double vision, blurred vision, drooping eyelids, slurred speech, difficulty swallowing, difficulty breathing, thick-feeling tongue, dry mouth, muscle weakness.
 <i>C. diff</i> (<i>Clostridioides difficile</i>)	1, 14	Infectious aerosols are the most likely route of laboratory-associated infections (LAI) and could serve as a reservoir for vegetative cells and spores.	2-3 days	Severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea.
 Coccidiomycosis, Valley Fever (<i>Coccidioides immitis, C. posadasii</i>)	3, 14	Inhalation of spores. Rarely, contact with broken skin can cause cutaneous infection.	1-3 weeks	Fatigue, cough, fever, shortness of breath, headache, night sweats, muscle aches or pains, rash on upper body or legs.
 Q fever (<i>Coxiella burnetii</i>)	1, 5, 9, 14	Inhalation of infectious aerosols. Accidental parenteral inoculation. Exposure to experimentally or naturally infected animals, their tissues, or body fluids. ID by inhalation is ~10 organisms.	9-39 days	Acute: Fever, chills, myalgia, arthralgia, headache, pneumonia, hepatitis.
 Dermatophytosis, Ringworm (<i>Microsporium, Epidermophyton and Trichophyton</i>)	3, 14	Contact with skin, nail lesions, contact with contaminated surfaces.	4-14 days after skin comes in contact with fungus	Ringworm can affect skin on almost any part of the body as well as fingernails and toenails. The symptoms of ringworm often depend on which part of the body is infected, but they generally include itchy skin, ring-shaped rash, red, scaly, cracked skin and hair loss.
 Encephalitis, EEE (Eastern Equine Encephalitis virus)	2, 5, 6, 12	Inhalation of infectious aerosols, accidental parenteral inoculation. Exposure to infected animals and mosquitoes in the lab.	1-10 days	Sudden onset of headache, high fever, chills, and vomiting; severe cases may progress to disorientation, seizures, or coma.

Completion of Federal Select Agent Program (FSAP) Forms



Form 3

(Only complete if there were exposures)

- Submitting lab must notify FSAP of exposures within 24 hours of confirmed BT agent identification by WSLH
- Submitting lab completes form 3 and submits to FSAP

Form 4

(Must always complete)

- WSLH notifies FSAP of identification of a select agent.
- WSLH completes their section of Form 4 as the identifying laboratory and submits to FSAP
- Submitting lab completes their section of Form 4 as the submitting laboratory and submits to FSAP



Destruction of All Positive Culture Media



- Check if patient has other cultures
 - If does, warn about positive BT isolate
- Gather all positive culture media
- **All isolates and positive cultures must be killed in your facility before transporting off site for disposal**
 - **Note: medical waste hauler can't destroy for you**
- Destruction methods:
 - Autoclave – solids and liquids
 - Chemical destruction
- Destruction must occur within 7 days of confirmation of a select agent



APHL Resource: “Clinical Laboratory Preparedness and Response Guide”

- *Decontamination of Select Agents Isolated in the Clinical Laboratory (see handout)*

Decontamination of Select Agents Isolated in the Clinical Laboratory



Select Agent regulations detailed in 7 CFR 331, 9 CFR 121 and 42 CFR 73 require that material containing an identified select agent must either be **destroyed or transferred** to a select agent registered facility within 7 days from confirmation (unless an extension is granted from CDC). Select agents may only be held more than 7 days from confirmation by facilities that are registered and approved by CDC and/or USDA to possess those specific select agents. Once an isolate from a patient specimen in a non-select agent registered clinical lab has been confirmed by a registered Laboratory Response Network (LRN) reference laboratory as a select agent, within 7 days the non-registered clinical lab must either **destroy** all other relevant patient specimens and cultures remaining in their possession or **obtain permission from CDC** to transfer them to the nearest LRN reference laboratory that is registered to possess the specific select agent.

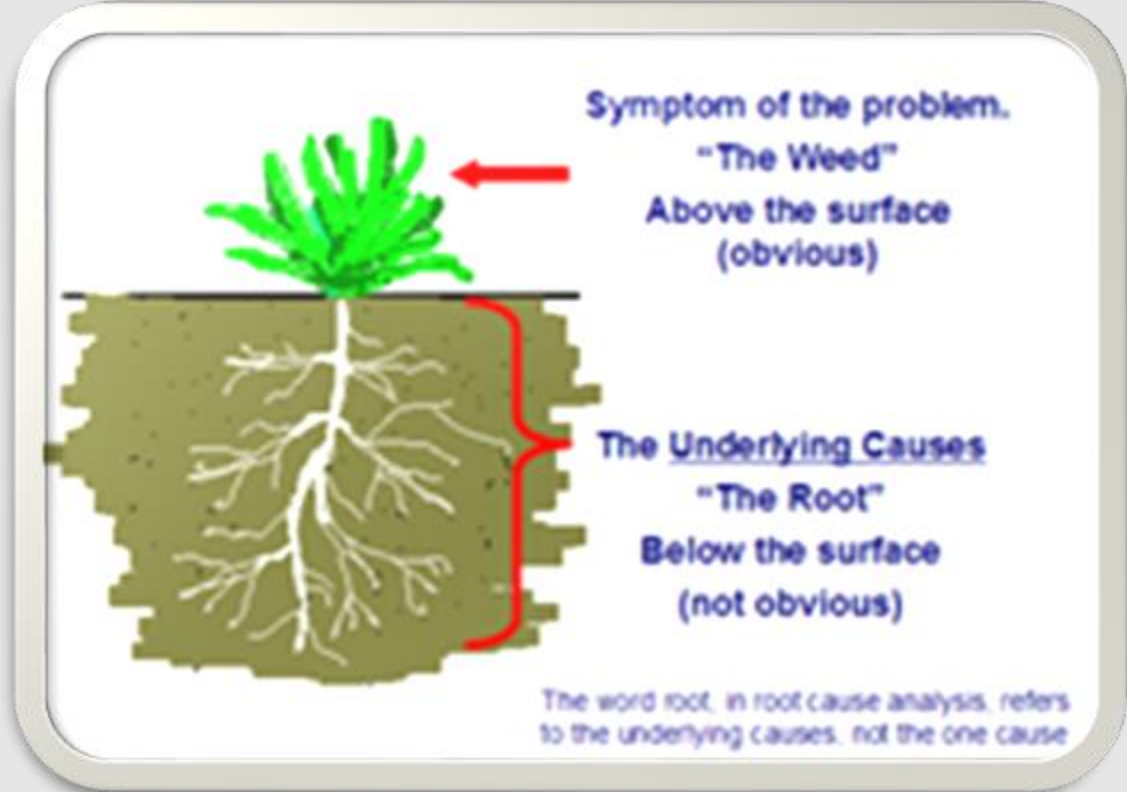
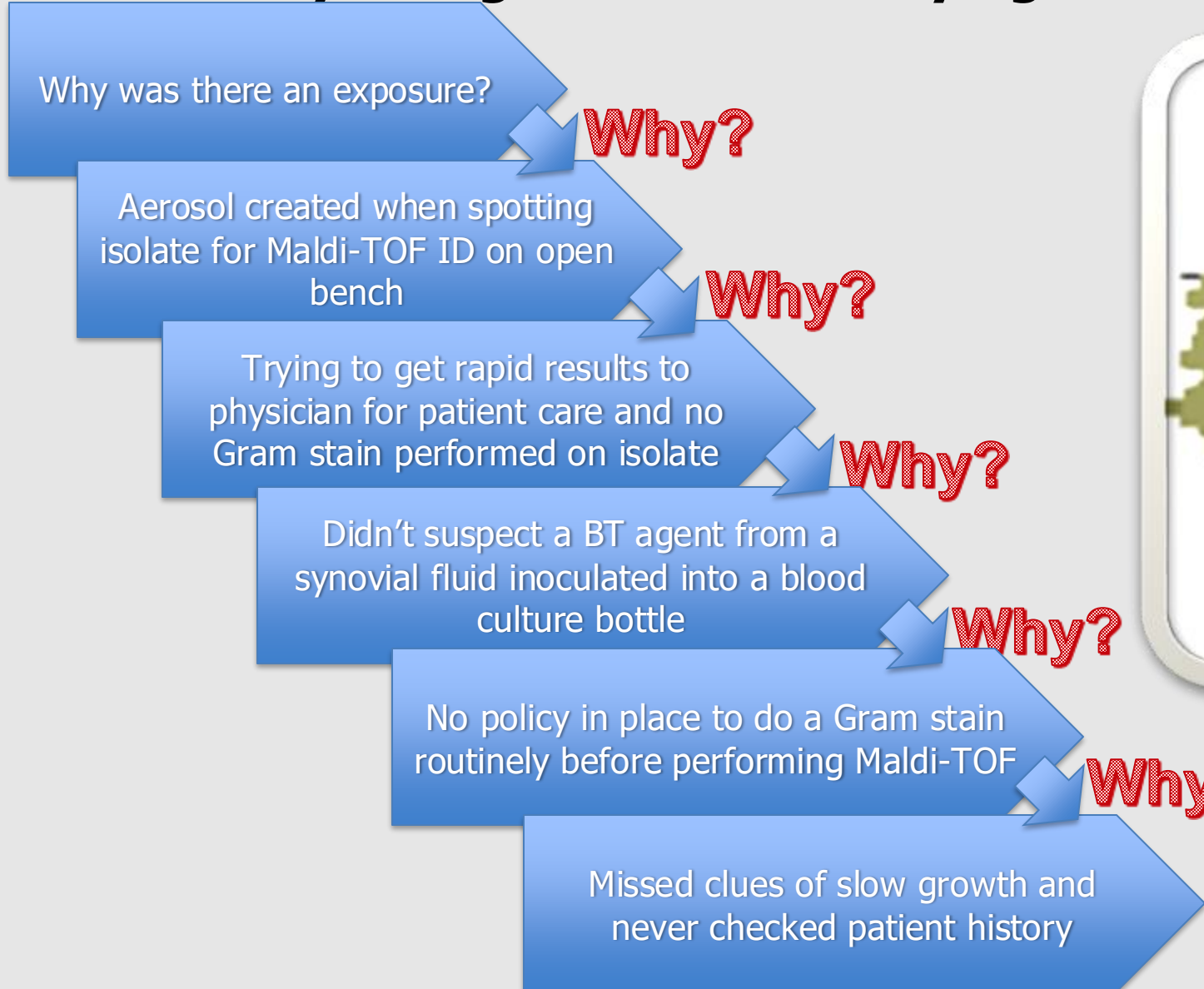
If a clinical lab chooses to **transfer the relevant specimens and cultures** after organism confirmation, the lab personnel will need to work with their LRN reference laboratory to ensure the proper paperwork (e.g., [APHIS/CDC Form 2](#)) and transfer protocols are followed in compliance with all applicable local, state, and federal shipping regulations, and carrier/courier requirements **prior to transport**. Transfer considerations should be discussed between clinical laboratories and LRN reference laboratories **before** LRN reference testing is conducted to avoid some potential shipping restrictions or dilemmas. If a facility does not have an autoclave on-site and chooses not to chemically decontaminate the cultures, all positive cultures including blood culture bottles must be transferred to an appropriate select agent registered laboratory approved and willing to accept the specific select agent material.





Determine Root Cause

Ask 5 "whys" to get to the underlying root cause of the problem?



Root Cause: Speed more important than safety?



Repeat Risk Assessment

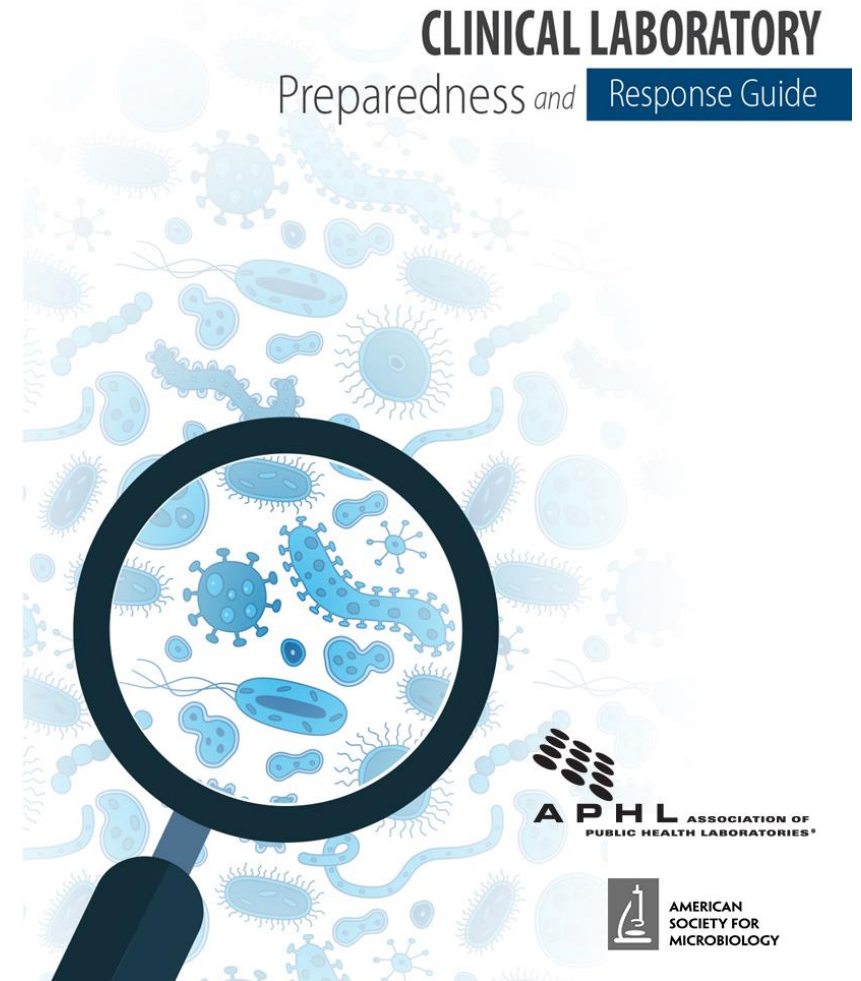
- What new hazards were identified in the root cause analysis?
 - Speed!
 - High volume!
 - Robotic! Not thinking about source and growth time.
- Evaluate the risk
 - High risk
- What else can be done to mitigate the risk?
 - Slow grower spot MALDI plates in BSC
 - Prepare and dry Gram stain in BSC
 - Read the Gram stain before running MALDI
 - Provide training
- Implement controls
- Review effectiveness and continue to adjust as needed



Updates coming in 2025 version



- The updated “Clinical Laboratory Preparedness and Response Guide” once again will serve as a complete reference document for Sentinel Clinical Laboratories.
- The updated guide will continue to assist the public health laboratory system in preparing and responding more quickly and efficiently to public health and laboratory emergencies.



Sections Reviewed and Updated

- Introduction
- Biosafety Basics
 - Decontamination of Select Agents Isolated in the Clinical Laboratory
 - Biothreat Agent Biosafety Awareness Flow Chart (NEW)
- Biosecurity Basics:
 - Biosecurity Checklist (NEW)
 - Biosecurity Risk Management Worksheet (NEW)
- Regulations That Impact Clinical Laboratories



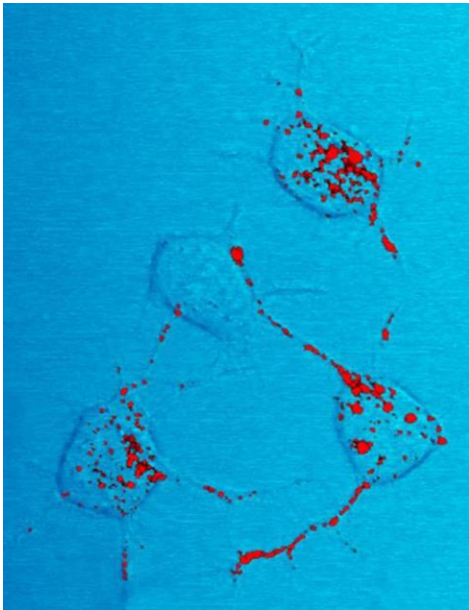
Sections Reviewed and Updated

- Quick Reference Guide to Specimen Collection of Suspected Agents of Bioterrorism
- Biothreat organism-specific technical content updated with the following key changes:
 - *Bacillus anthracis* and *Bacillus cereus* biovar *anthracis*
 - New *Brucella* spp. (Formerly *Ochrobactrum* spp.)
- Packaging and Shipping
 - APHL P&S Tool Kit



Three New Sections Added

- Biosafety Training and Competency
- MALDI-TOF MS
- Prion Diseases and Job Aid



Prion photomicrograph
CDC PHIL



New and Updated Job Aids

- Decontamination of Select Agents Isolated in the Clinical Laboratory
- Biothreat Agent Biosafety Awareness Flow Chart (NEW)
- Biosecurity Checklist (NEW)
- Biosecurity Risk Management Worksheet (NEW)
- Prion Diseases Job Aid
- MALDI-TOF MS Safety Job Aid



Decontamination of Select Agents Isolated in the Clinical Laboratory

Decontamination of Select Agents Isolated in the Clinical Laboratory

Select Agent regulations detailed in 7 CFR 331, 9 CFR 121 and 42 CFR 73 dictate that material containing an identified select agent must be either **destroyed or transferred** to a select agent registered facility within 7 days from confirmation (unless an extension is granted from CDC). Select agents may only be held more than 7 days from confirmation by facilities that are registered and approved by CDC and/or USDA to possess those specific select agents. Once an isolate from a patient specimen in a non-select agent registered clinical lab has been confirmed by a registered laboratory response network (LRN) reference laboratory as a select agent, within 7 days the non-registered clinical lab must either **destroy** all other relevant patient specimens and cultures remaining in their possession, **or obtain permission from CDC to transfer** them to the nearest LRN reference laboratory that is registered to possess the specific select agent.

If a clinical lab chooses to **transfer the relevant specimens and cultures** after organism confirmation, the lab personnel will need to work with their LRN reference laboratory to ensure the proper paperwork (e.g., [APHIS/CDC Form 2](#)) and transfer protocols are followed in compliance with all applicable local, state, and federal shipping regulations, and carrier/courier requirements **prior to transport**. Transfer considerations should be discussed between clinical laboratories and LRN reference laboratories **before** LRN reference testing is conducted to avoid some potential shipping restrictions or dilemmas. If a facility does not have an autoclave on-site and chooses not to chemically decontaminate the cultures, all positive cultures including blood culture bottles must be transferred to an appropriate select agent registered laboratory approved and willing to accept the specific select agent material.

If a non-registered clinical lab decides to **destroy the relevant specimens and cultures** in-house, inactivation using an on-site autoclave or chemical decontamination method must be performed before final disposal or transferring the items to a medical waste contractor for destruction and final disposal. Specimens associated with an identified select agent cannot be directly discarded into the biohazardous waste stream like other regulated infectious medical waste materials because the material would be classified as Category A waste and restricted according to both the select agent regulations and the US Department of Transportation Hazardous Material regulations (49 C.F.R., Parts 171-180). Autoclaving is the preferred method of destruction, however when an autoclave is not available, chemical decontamination may be the only feasible option. For both chemical inactivation decontamination procedures below, the clinical laboratory should note the date, amount/quantity of material being destroyed, method of destruction, and the laboratorian(s) performing the procedures for record keeping purposes.

Non-registered clinical labs are not required to have a validated select agent inactivation protocol but may use these decontamination procedures as a recommended best practice.

Chemical Inactivation Decontamination Process for Samples and Cultures

1. Prepare a fresh (daily) 10% (1:10) solution of household bleach in a receptacle large enough to submerge all containers/plates containing the select agent.
2. Working in a biological safety cabinet (BSC), **slowly** and completely immerse open sample/culture containers in the bleach solution.
3. Leave the open and submerged containers in the bleach solution overnight.
4. Once overnight inactivation is complete, turn the sink faucet on and discard the bleach solution down the drain with running tap water.
5. Place the inactivated sample/culture plates and containers in a biohazard bag and discard them with the other biohazardous waste that is transported off site by a medical waste management contractor for final treatment and disposal.

Chemical Inactivation Decontamination Process for Blood Culture Bottles

If an organism is subcultured from a blood culture bottle and a LRN reference laboratory confirms the organism as a select agent, or if the patient is diagnosed with a select agent such as smallpox or a viral hemorrhagic fever (VHF), the associated blood culture bottles and any additional bottles or cultures that would contain the organism, must be decontaminated before transport off site within 7 days from confirmation. Autoclaving is the preferred destruction method since the contents in these bottles cannot be easily decontaminated using chemical inactivation decontamination.

- Bring all needed materials into a BSC including the blood culture bottle(s), a syringe, and a small amount of undiluted household bleach (e.g., ~50mL per blood culture bottle to decontaminate).
- Working in a BSC, the blood culture bottles can be chemically decontaminated by adding straight (not diluted) household bleach to the bottle to obtain a final concentration of 1-2% sodium hypochlorite (20 - 40% household bleach and ~10,000 ppm available chlorine) within the bottle. The higher undiluted bleach concentration works well for inactivation and accounts for the large amount of organic material present.
- Cover the top of the bottle with a disinfectant soaked gauze pad (e.g., 10% bleach) to contain any splashes and **slowly** inject the undiluted bleach into the bottle(s).
- Discard the used syringe in the sharps container inside the BSC.
- Let the bottle(s) sit overnight in the BSC and post a warning/safety sign for it.
- Package the inactivated bottle(s) with other biohazardous waste that is transported off site by a medical waste management contractor for final treatment and disposal.

Toxin Inactivation

For specimens to which there may be a suspected or confirmed select agent toxin present, the clinical lab should consult with their LRN reference laboratory about specific concerns and inactivation methods. In general, most toxins associated with biological specimens can be easily inactivated or denatured by steam sterilization, dry heat or chemical means such as sufficient contact time with a fresh (daily) 10% solution of prepared bleach, or another chemical such as sodium hydroxide (NaOH, 0.1N). Consult the Biosafety in Microbiological and Biomedical Laboratories (BMBL), section VIII-G for specific toxin information and recommended inactivation methods.

<https://www.cdc.gov/labs/BMBL.html>

Preparation of Bleach Solutions Containing 5.25 – 6.15% NaOCl:

Dilution	Chlorine (ppm)
None / straight, concentrated bleach	52,500 – 61,500
(10% bleach) 1:10, or 1½ cup:1 gallon, or 100mL:1000mL	5,250 – 6,150
(5% bleach) 1:20, or ¾ cup:1 gallon	2,625 – 3,075
(1% bleach) 1:100, or ¼ cup:1 gallon	525 – 615

(PPM = Parts per million), NaOCl = sodium hypochlorite

Decontamination of Material That May Contain Select Agent Spores

If there is a concern that select agent spores (e.g., *Bacillus anthracis* spores) may be present, or if there is a need to decontaminate material that may contain spores, stronger disinfectants than those used routinely may be required. Clinical labs should consult with their LRN reference laboratory about specific concerns and decontamination methods. The pH of a bleach solution may also need to be checked and amended in order to efficiently decontaminate spores by chemical inactivation methods. Consult the EPA list of approved disinfectants for additional info.

<https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>

Notes: Bleach is usually between 5.25% - 6.15% sodium hypochlorite, or 52,500 – 61,500 ppm available chlorine, but will vary depending on the manufacturer and if it is "regular" strength (typically 5.25%) vs. "ultra" strength. "Ultra" strength products are typically about 6.15%, but the germicidal Chlorox brand can be up to ~8.25%. It is important to know the concentration of the bleach being used to ensure the desired final concentration will be obtained when preparing the solution. Different bleach products may have different concentrations of hypochlorite. Hypochlorite concentrations will degrade over time and with storage conditions. Working bleach solutions will also be affected and have a decreased efficacy by the amount of organic material that may be present in the material intended to be decontaminated. Follow all manufacturer product specific instructions.

References:

1. <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/disinfection-methods/chemical.html#Chlorine>
2. <https://www.aphis.gov/programs/preparedness/Biosafety-and-Biosecurity/Documents/Practical%20Disinfection%20Guidance%20for%20the%20Clinical%20Laboratory.pdf>
3. <https://www.selectagents.gov/tqd-intro.html>
4. <https://multimedia.3m.com/mws/media/7359760/disinfection-with-bleach-tech-talk.pdf>
5. <https://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
6. <https://www.selectagents.gov/regulations/index.htm>
7. <https://www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-overview>
8. <https://www.cdc.gov/labs/BMBL.html>
9. <https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants>

Biothreat Agent Biosafety Awareness Flow Chart

Biothreat (BT) Agent Biosafety Awareness Flow Chart

Note: Always verify that a biosafety cabinet (BSC) is certified and functioning properly prior to performing any work in it. (If a BSC is unavailable see the "Biosafety" section in this reference for alternative safety measures.)

Note: Heat or methanol fixation may not necessarily kill all organisms in a dried smear, therefore, there is a very low risk of aerosol production if the slide would drop and break.

Blood Cultures

Blood culture instrument signals there is a positive bottle.

Remove positive bottle to perform a Gram stain.

- Before staining, determine how long the bottle has been incubating. **If >24 h consider this may be a BT agent.**
- Is there any patient history or a clinical note in the patient record to indicate the need to consider a possible BT agent?
- Always make smears, allow to dry and perform any heat fixation (which can create aerosols) in a **certified biosafety cabinet (BSC)**.

Gram stain fixed slide and examine slide.
Suspect a BT agent if:

- See large boxcar like Gram positive bacilli, with or without spores.
- See tiny GNGB.

Working in a BSC, subculture positive bottles suspected of containing a BT agent to BAP, CHOC, and MAC/EMB agar plates. Tape plates shut and label. "Possible BT agent – open in a BSC".

Wound and Lower Respiratory Cultures

Always check if there is any patient history, or a clinical note in the patient record to indicate the need to consider a possible BT agent?

Working in a BSC, examine plates at 24 h for growth. If no growth or only slight growth and tiny colonies, re-incubate plates.

Working in a BSC, examine plates at 48 h for growth. Note the following:

- Time to growth.
- Which plates have growth.
- Colony morphology.
- Any hemolysis on BAP.

STOP – DO NOT put the organism on MALDI –TOF or other automated ID system unless all possible BT agents have been ruled-out. (See *MALDI-TOF Safety Guide*)

Gram stain fixed slide and examine slide. Dependent on Gram stain result, refer to the APHL "Recognize. Rule-out. Refer." bench guide and the ASM agent specific "Sentinel Level Clinical Laboratory Guidelines" to determine further rule-out testing to perform. **Always perform rule-out testing in a BSC.**

Working in a BSC, make a smear of the colony growth for a Gram stain and allow to dry in the BSC. (See note under Blood Cultures above) Also perform an oxidase and tube catalase on the colony growth.

If unable to rule-out all BT agents **contact the ordering physician** to discuss whether the patient's symptoms could indicate a possible BT agent.

Contact your LRN laboratory to notify them you have isolated a possible BT agent you are unable to rule-out and determine your next steps.

Check to see if the patient has cultures from other specimens that may grow the same organism. Make a note in the patient electronic record on all other cultures to **perform all work in a BSC** due to a suspect BT agent and flag all culture media. (e.g., tape/bag plates, add stickers, etc.)

12/07/2022

Biosecurity Checklist

BIOSECURITY CHECKLIST		DECEMBER 2024
<h2>A Biosecurity Checklist: Developing A Culture of Biosecurity</h2>		
<h3>Background</h3> <p>There is an inherent risk in a laboratory handling any infectious agents. Biosafety and biosecurity practices should be adhered to in all laboratories that receive potentially infectious material in order to ensure laboratory personnel, public and environmental safety. Recent incidents involving biosafety and biosecurity lapses highlight the need to enhance the culture of biosafety and biosecurity across the laboratory community in the United States. This checklist in conjunction with the *Clinical Laboratory Biosafety Risk Management Program Assessment Checklist were developed by the Association of Public Health Laboratories to serve as a starting point for clinical laboratories to assess the biosafety and biosecurity measures that they have in place.</p>		
<h3>Intended Use</h3> <p>This checklist is intended for any laboratory performing testing on infectious agents or clinical specimens that could contain infectious agents. It is designed to provide laboratories with the broad recommendations for components that should be considered for inclusion in any laboratory's biosecurity policy.</p>		
<p>The checklist consists of six sections:</p> <ol style="list-style-type: none"> 1. Risk Assessment 2. Selection of Security Practices <ul style="list-style-type: none"> • Biosafety Level • Engineering/IT Controls • Laboratory Practices and Policies 3. Biosafety Competencies 4. Biosafety Orientation and Training 5. Audits, Monitoring and Safety Committee 6. Administrative Controls 		
1		A Biosecurity Checklist

Facility: _____

Address: _____

City: _____

State/Zip: _____

Lab Director: _____

Contact Info: _____

Safety Officer: _____

Contact Info: _____

BIOSECURITY RISK ASSESSMENT				
Yes	No	Not Applicable	RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a written policy and/or a standard operating procedure (SOP) for performing biosecurity risk assessments?	Biosecurity Risk Management Worksheet Sendle National Laboratories has a lot of good information about biosecurity http://www.sendle.gov/about/index.html APHL Biosafety and Biosecurity Resources https://www.aphl.org/programs/preparedness/Pages/Biosafety-Biosecurity-Resources.aspx
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Do biosecurity risk assessments consider all assets (e.g., agents, personnel, data, sensitive information, equipment, and patients), potential threats (internal and external) and vulnerabilities?	Biosecurity Risk Assessment Worksheet It is recommended that biosecurity risk assessments follow these steps: <ul style="list-style-type: none"> • Identify & Inventory Assets • Assess Potential Threats and Vulnerabilities • Prioritize the Threats/Risks of Specific Scenarios • Develop Overall Risk Management Program • Re-evaluate and Revise Biosecurity Plan
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Has the person performing the biosecurity risk assessment received training and are they experienced in risk assessments?	BioRisk Manager will assist with training if needed Biosecurity Risk Assessment Worksheet
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is a biosecurity risk assessment conducted: <ul style="list-style-type: none"> • At least annually • After any biosecurity-related incident • Changes to the facility • After drills/exercises • After plan audits 	

3

A Biosecurity Checklist

SELECTION OF BIOSECURITY PRACTICES				
BIOSAFETY LEVEL				
Yes	No	Not Applicable	RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are biosafety levels selected based on the BMBL recommendations?	More information on the selection of biosafety level is available on pages 32-69 of CDC's BMBL 6 th Edition
ENGINEERING/IT CONTROLS				
Yes	No	Not Applicable	RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there controlled access to biosafety level 2 and 3 laboratories?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there controlled access to high consequence agents (e.g., locked cabinet, refrigerator)?	

Biosecurity Risk Management Worksheet

Biosecurity Risk Management Worksheet

Step 1: Identify and Prioritize Assets

--

Step 2: Assess Potential Threats and Vulnerabilities

--

Step 3: Analyze the Risk of Specific Security Scenarios (Threat/Risk Prioritization Chart below)

--

Step 4: Plan and Develop an Overall Biosecurity Program including Mitigation

--

Step 5: Re-evaluate the Laboratory's Biosecurity Program and Modify Protection Measures

--

Physical Security and Access Controls

<i>Potential Problems (Vulnerabilities)</i>	<i>Solutions (Possible Preventative Measures)</i>

Personnel Management

<i>Potential Problems (Vulnerabilities)</i>	<i>Solutions (Possible Preventative Measures)</i>

Inventory & Accountability

<i>Potential Problems (Vulnerabilities)</i>	<i>Solutions (Possible Preventative Measures)</i>

Transport of Agents

<i>Potential Problems (Vulnerabilities)</i>	<i>Solutions (Possible Preventative Measures)</i>

Prion Diseases Job Aid

Prion Diseases Job Aid

Specimen Types

There are limited clinical laboratories that perform diagnostic testing for prion diseases (e.g., National Prion Disease Pathology Surveillance Center (NPDSPC)). Specimens are grouped into high infectivity, low infectivity, and no detectable infectivity categories based on potential for quantity of prions present. As such, laboratories serving as intermediaries (i.e., packaging and shipping to NPDSPC) or performing other diagnostic testing on the same specimen should establish appropriate risk level handling protocols. The NPDSPC performs lab testing for central nervous system tissue (e.g., brain biopsy (gray matter)), cerebrospinal fluid, and blood specimen types. Since central nervous system tissue (CNS) (e.g., brain tissue, spinal cord) and coverings are the highest infectivity risk (e.g., high prion concentrations) sample types, institutions/hospitals/facilities are discouraged from sampling these high risk tissues from viable patients with suspected or confirmed prion disease. However, if CNS tissue is sampled, appropriate precautions must be taken from collection, handling, and transport to the NPDSPC. Tissue may be sampled in autopsy; however, it is advised that autopsy only be conducted on suspected/confirmed patients by facilities that have experience performing autopsy on prion disease confirmed patients. The primary specimen utilized for prion diagnosis in viable patients is cerebrospinal fluid (CSF). Blood may be used for PRNP Genetic Testing for diagnosing genetic prion disease. It is likely that prions are also found in the kidney, liver, lung, spleen, thymus, lymph nodes, and placenta; laboratorians should utilize standard precautions when handling all samples, including those fixed in formalin.

Clinical Laboratory Risks / Laboratory Specific Safety Concerns

Clinical laboratories should request advanced warning from Infection Prevention and providers regarding referral of specimens from patients with suspected CJD. Optimally, interventional Radiology staff should contact Infection Prevention when samples are collected to ensure that initial laboratory processors utilize standard precautions and a Class II biological safety cabinet (BSC).

The primary hazard in the lab is accidental parenteral (traumatic) inoculation; but there is also risk of infection from specimen spills or splashes. Adherence to Standard Precautions during any primary specimen handling and laboratory procedure will reduce the risk of infection. Laboratorians working with prion-infected or contaminated material should take extreme care to avoid accidental puncture of the skin i.e., follow a risk reduction protocol.

Biosafety level 3 (BSL-3) facilities, practices, and containment equipment are recommended for dedicated activities involving prions. If a BSL-3 facility is unavailable for a laboratory performing prion specific testing or research, work may be performed in a BSL-2 with enhanced precautions. The ability to work under BSL-2 with enhanced precautions depends on the nature of the manipulations that will be done as well as the quantity of prion burden and type of specimens utilized i.e., necropsy or autopsy tissues. At a minimum, laboratorians performing prion specific diagnostic testing should wear gown, eye protection and gloves (Standard precautions) and work within a Class II BSC with enhanced precautions. Any tasks involving potential for traumatic inoculation i.e., use of a microtome or changing the blade on a microtome should include use of cut resistant gloves to avoid parenteral inoculation.

Clinical laboratories should conduct their own facility-specific risk assessment(s) and develop appropriate precautionary procedures prior to any work with potential prion-containing specimen

samples. They are also encouraged to consult with their local or state public health department, public health laboratory, the CDC, or other prion related groups such as NPDSPC, if there are any questions or concerns.

Occupational Exposure, Treatment, and Post-Exposure Management

Prions are transmissible by inoculation, ingestion, or transplantation of infected tissues or homogenates. Prion infectivity is high in the brain, other CNS tissues, and eyes while lower infectivity is associated with lymphoid tissues and CSF. While cases of occupational exposure to prion disease in healthcare workers have been reported, there have been no reported confirmed cases of occupational transmission of transmissible spongiform encephalopathy (TSE) to humans within the clinical diagnostic setting. Currently, there is no cure, immunization, or prophylaxis for prion diseases. Treatment remains supportive, and no specific therapy has been shown to stop the progression of these diseases. There is a distinct difference in occupational risk levels between routine clinical diagnostic labs and prion disease diagnostic labs as well as prion disease research laboratories.

In case of exposure: <https://www.cdc.gov/prions/cjd/treatment.html>

- Contamination of unbroken skin with internal body fluids or tissues: wash with detergent and abundant quantities of warm water (avoid scrubbing), rinse, and dry.
 - Brief exposure (1 minute, to 0.1N NaOH or a 1:10 dilution of bleach) can be considered for maximum safety. *Extreme caution needs to be taken if applying these chemicals to skin.*
- Needle sticks or lacerations: gently encourage bleeding; wash (avoid scrubbing) with warm soapy water, rinse, dry and cover with a waterproof dressing (sutures may be necessary for larger wounds). Report according to hospital or healthcare facility/laboratory procedure.
- Splashes into the eye or mouth: irrigate with either saline (eye) or tap water (mouth); report according to hospital or healthcare facility/laboratory procedures.

Infection Control

The CDC and WHO provide infection control related information here:

- <https://www.cdc.gov/prions/cjd/infection-control.html>
- <https://apps.who.int/iris/handle/10665/66707>

Decontamination

Prions are notoriously difficult to inactivate and are characterized by relative resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and harsh chemicals such as formalin, beta-propiolactone, and alcohols. More effective protocols include enzymatic treatments with sodium dodecyl sulfate (SDS), proteinase K (PK), and ~~protease~~ three-stage procedure; vaporized hydrogen peroxide (HVP), 4% SDS in 1% acetic acid at 65–134°C, or mildly acidic hypochlorous acid. The safest and most unambiguous method for ensuring that there is no risk of residual infectivity on contaminated surgical instruments and other materials is to discard and destroy them by incineration. Contaminated disposable surgical instruments or materials can be incinerated at 1000°C (1832°F) or greater. However, disposable instruments are not always feasible. Sterilization of reusable surgical instruments and decontamination of surfaces are performed in accordance with recommendations described by the CDC and the WHO infection control guidelines. See Annex III.2. Autoclave/chemical methods for heat-resistant instrument of the *WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies* report for further guidance. Table 3 (*Tissue Preparation for Human CJD and Related*

Diseases) and Table 4 (*Prion Inactivation Methods for Reusable Instruments and Surfaces*) within the Prion Disease Section of the BMBL provides additional procedure information. However, be aware that the BMBL instructions are largely geared toward research based facilities working with purified prions instead of routine clinical laboratories who do not perform prion specific diagnostic testing.

- <https://apps.who.int/iris/handle/10665/66707>
- <https://www.cdc.gov/labs/BMBL.html>

Testing

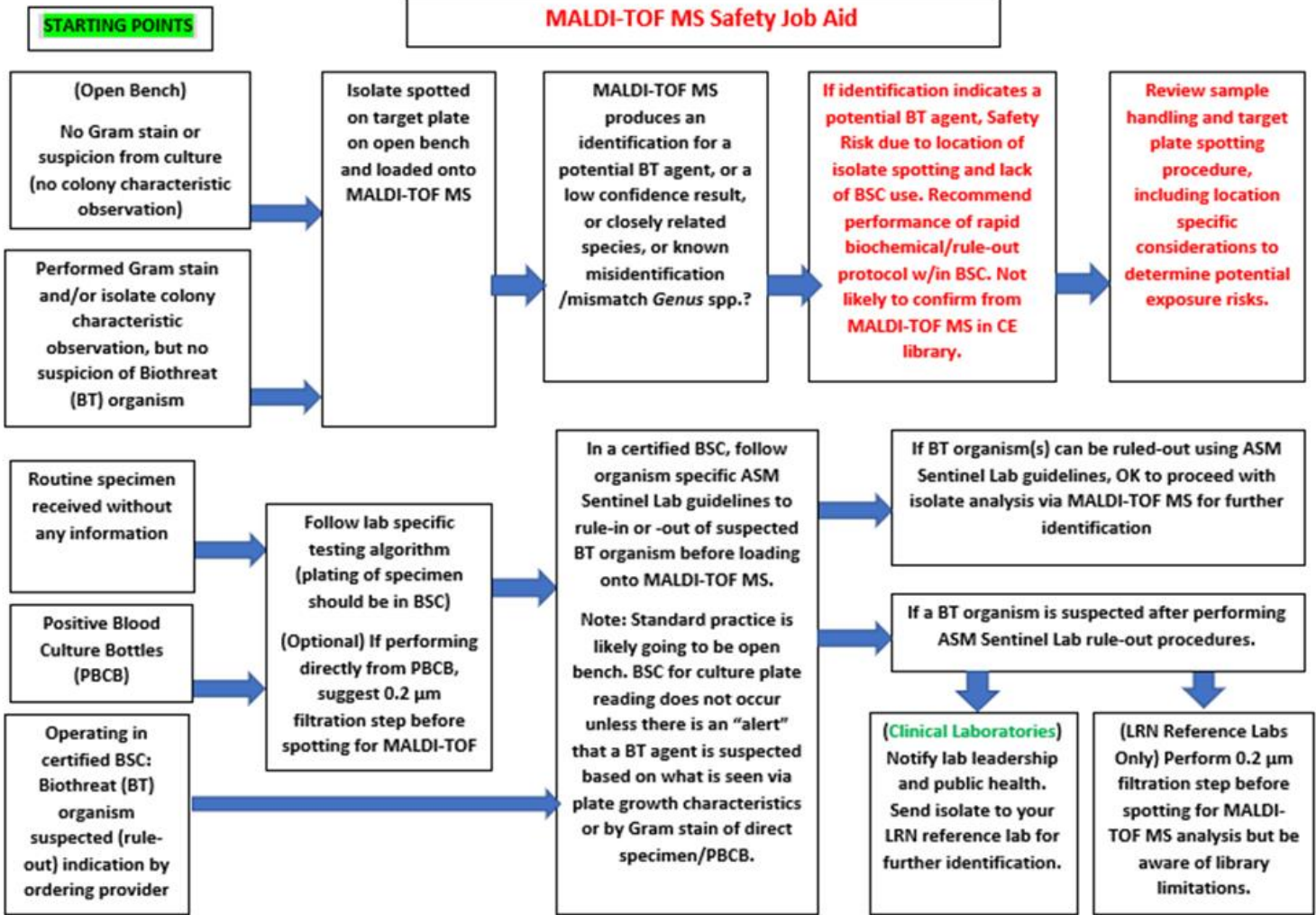
Several tests can help diagnose CJD including electroencephalography (EEG), CSF-based tests for Prion markers e.g., real-time quaking-induced conversion (RT-QuIC), Total Tau (ELISA), and 14-3-3γ (ELISA), and magnetic resonance imaging (MRI). Diagnostic criteria according to the CDC for sporadic, iatrogenic, or familial CJD can be found here: <https://www.cdc.gov/prions/cjd/diagnostic-criteria.html> Genetic testing information, research studies, and clinical trials, as well as information about other diagnosis and management resources can be found here: <https://ghr.nlm.nih.gov/condition/prion-disease#diagnosis>. Blood may be used only for PRNP Genetic Testing.

Shipping

Prion samples, regardless of the type of specimen, are acceptable to be classified and shipped as a UN 3373, Biological Substance, Category B material. Laboratories should communicate with the diagnostic testing laboratory and any couriers/carriers regarding additional or specific instructions and required documentation (e.g., testing submission form). The NPDSPC provides additional resources and guidance for shipping by sample type, and information about obtaining Prion Tissue Kits.

- <https://case.edu/medicine/pathology/divisions/national-prion-disease-pathology-surveillance-center/resources-professionals/contact-and-shipping-information>

MALDI-TOF MS Safety Job Aid



Acknowledgements

- **Project Lead:** Shoolah Escott
 - Email: Shoolah@gmail.com
- **Team:**
 - Erin Bowles
 - Andrew Cannon
 - Melissa D'Amico
 - Crystal Fortune
 - Phil Lee
 - Steve Mahlen
 - Rob Nickla
 - Mike Perry
 - Amity Roberts
 - Betsy Weirich
- **Additional Assistance:**
 - APHL PHPR Group
 - Amanda Moore
 - Courtney Freestone
 - APHL MARCOM
 - Ishita Gulati



designed by  freepik.com

Partners in Laboratory Preparedness and Response

- American Society for Microbiology: Sentinel Level Clinical Microbiology Laboratory Guidelines
- College of American Pathologists: Laboratory Preparedness Exercise
- MOU: Diagnostic Surge Testing Capacity for Public Health Emergencies (Many partners)



The screenshot shows a webpage from the American Society for Microbiology (ASM). The article title is "Laboratory Response Network (LRN) Sentinel Level Clinical Laboratory Protocols", dated Nov. 20, 2013. The text states that ASM, in coordination with APHL, has updated protocols for Sentinel Level Clinical Laboratories. It mentions that these protocols are designed to offer LRN Sentinel Level Clinical Laboratories standardized, practical methods and techniques to rule out microorganisms suspected as agents of bioterrorism, or to refer specimens to public health laboratories for confirmation. A "Related Content" section lists other articles such as "Novel Coronavirus Lab Protocols and Responses: Next Steps" and "20 Years of the Lab Response Network with Julie Villanueva".



The CAP logo features a globe and the text "cap Moving together". Below it is the slogan "Every number is a life." To the right is a photograph of a laboratory technician in a blue lab coat and gloves, working with a pipette in a lab setting.

Help your laboratory prepare for a potential public health emergency with the CAP's Laboratory Preparedness Exercise (LPE)

The Laboratory Preparedness Exercise was developed as a collaborative effort between the College of American Pathologists (CAP), the Centers for Disease Control and Prevention (CDC), and the Association of Public Health Laboratories (APHL).

The exercise tests the preparedness of laboratories across the US and Canada to handle potential public health emergencies related to bioterrorism agents.

- Participating laboratories receive live organisms that exhibit characteristics of bioterrorism agents or demonstrate epidemiologic importance.
- If a bioterrorism agent is suspected, laboratories are expected to respond following Sentinel Level Clinical Microbiology Laboratory Guidelines.
- All agents provided are excluded from the CDC's select agent list.
- Laboratories must have a certified Class II Biological Safety Cabinet and be capable of handling Category A and B agents.
- LPE includes three challenges per shipment/two shipments per year.

Centers for Disease Control and Prevention
Center for Surveillance, Epidemiology and Laboratory Services
Division of Laboratory Systems
MEMORANDUM OF UNDERSTANDING
for
Diagnostic Surge Testing Capacity for Public Health Emergencies

This Memorandum of Understanding (MOU) sets forth the terms and understanding between Advanced Medical Technology Association (AdvaMed), American Clinical Laboratory Association (ACLA), Association for Molecular Pathology (AMP), Association of Public Health Laboratories (APHL), College of American Pathologists (CAP), Council of State and Territorial Epidemiologists (CSTE), Food and Drug Administration (FDA), National Independent Laboratory Association (NILA), CDIA Inc., Administration for Strategic Preparedness and Response (ASPR), and the Centers for Disease Control and Prevention/ Office of Laboratory Science and Safety/Division of Laboratory Systems (CDC/OLSS/S&S) (hereinafter referred to collectively as "Parties"). The Parties represented in this MOU agree to collaborate on enhancing laboratory testing surge capacity outside of CDC and public health laboratories before and during public health emergencies (PHEs).

BACKGROUND

An emerging pathogen that spreads quickly and/or has the potential to cause significant disease in humans, such as influenza, Zika, or SARS-CoV-2 virus, could result in demands for a high volume of laboratory diagnostic testing that exceeds the current testing capacity of the United States (U.S.) governmental public health laboratory system. Public health laboratories (PHLs) have expertise characterizing infectious organisms, handling clinical and non-clinical samples, and many have the ability to scale up routine operations to provide surge capacity during a response. The capability and capacity of PHLs was utilized during several outbreaks, including Anthrax 2001, the response to the Middle East Respiratory Syndrome, and Ebola outbreaks. However, public health laboratory systems are not currently designed to handle and execute diagnostic testing at a large scale and scope beyond the initial critical phases of public health emergencies. Furthermore, in the early phase of an emergency response, FDA-authorized tests and testing platforms may be inherently limited and may not be optimized for high throughput. The need to supplement public health laboratory diagnostic testing capacity has been demonstrated in previous virus outbreaks. At the advent of the H1N1 influenza virus outbreak, hospital-based clinical laboratories responded rapidly and effectively and the need for a coordinated and streamlined response from both public health and clinical diagnostic laboratories became apparent. The Zika virus outbreak resulted in the engagement of large independent laboratories with nationwide facilities. At the same time, hospital-based laboratories served the diagnostic needs of their patient populations. Most recently, the extensive demands for diagnostic testing during the coronavirus disease (COVID-19) pandemic quickly extended beyond public health laboratories and independent laboratories to other Clinical Laboratory Improvement Amendments (CLIA)¹ certified testing facility types.

¹ <https://www.cdc.gov/Regulations-and-Guidance/legislation/CLIA>

Resources

ASM: [LRN Sentinel Level Clinical Laboratory Protocol](#)

CAP: [Laboratory Preparedness Exercise](#)

CDC:

- [Laboratory Outreach Communication System](#)
- [OneLab Network](#)

APHL:

- [Sentinel Clinical Laboratory Definition](#)
- [Benchcards](#)
- [Biothreat Agents Poster](#)
- [Clinical Laboratory Preparedness and Response Guide](#)
- [Biothreat Response: Sentinel Laboratory Training Toolbox](#)
- [Biosafety and Biosecurity](#)

www.aphl.org

Recognize. Rule-Out. Refer.

Biothreat Agent Bench Cards for the Sentinel Laboratory





For questions, contact your designated LRN Reference Level Laboratory:

(LRN Reference Level Laboratory Name)

(Phone Number)

Biosecurity Exercises

A Toolkit for Public Health and Clinical Diagnostic Laboratories

Laboratory biosecurity refers to the measures that are taken to safeguard sensitive biological materials and information against theft, loss, misuse, diversion or intentional release. Laboratory biosecurity policies hold laboratories accountable for the management and use of the biological materials and information they possess to prevent harm to human, animal and plant health, as well as food and environmental safety.

This toolkit is designed to equip laboratories with the knowledge and resources necessary to enhance biosecurity measures within their facilities, strengthen existing biosecurity protocols or establish new ones—thereby ensuring the safety of both laboratory staff and the community. By providing biosecurity exercise examples and exercise design and development sections throughout the tool, the Association of Public Health Laboratories (APHL) aims to empower laboratories to proactively identify and mitigate potential biosecurity risks. Our intent is to foster a proactive approach to biosecurity, emphasizing prevention, preparedness and response. We encourage all users to engage with the exercises, leveraging insights gained to strengthen their laboratory's biosecurity readiness.

BACKGROUND

Every laboratory must take steps to protect the environment, facility, personnel, and any samples or confidential information in its care. To ensure sufficient safeguards are in place for these purposes, laboratories must train personnel, assess competency in the desired knowledge and skills, and test the engineering and administrative systems designed to protect critical assets. The purpose of this toolkit is to provide guidance and practice exercises for developing laboratory biosecurity drills and exercises with the goal to prevent the threat of biological agent loss, theft, misuse, diversion, unauthorized access or intentional release.

Events such as the 1984 Rajnesheve Bioterror Attack, the 1996 Delta Isotome committed by a clinical laboratory scientist, and the 2001 Amerithrax mailings, along with the ongoing, expressed threat of bioterrorism by terrorist groups and radicalized individuals demonstrate vulnerabilities to acts of bioterrorism and biothreats and the importance of laboratory biosecurity training. These events have prompted laboratory leadership to evaluate the need for creating, implementing, and/or enhancing the security measures for biological agents and toxins in their facilities.

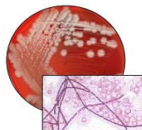
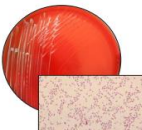
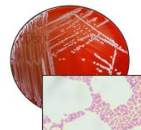
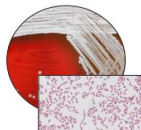
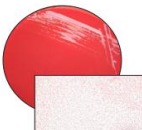
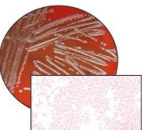
To mitigate these threats, the *Federal Select Agent Program (FSAP)*—managed through the US Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Agriculture Select Agent Services—regulates the acquisition, use, storage and transfer of select agents and toxins through the development, implementation and enforcement of the Federal Select Agent Regulations. FSAP is currently the only federal program requiring the development of a laboratory biosecurity program; however, the list of biological materials that could be misused for malicious purposes extends beyond the *List of Select Agents and Toxins*. Therefore, while not all laboratories are registered under FSAP, the application of laboratory biosecurity principles may enhance overall laboratory management, safety and security.

CONTENTS

- 1... Background
- 2... Exercise Design and Development
Discussion-based Exercises...3
Operations-based Exercises...3
- 4... Exercise Evaluation
- 5... Training and Exercise Evaluation Form
Evaluation Form Template...5
Example Evaluation Form...7
10. Appendix:
Laboratory Security Exercise Examples

APHL Biosecurity Exercises Toolkit | 1

BIOTHREAT AGENTS

 <p>ANTHRAX <i>Bacillus anthracis</i></p> <ul style="list-style-type: none"> • Large Gram positive rods (1-1.5 µm x 3-5 µm) • Smears of clinical specimens: <ul style="list-style-type: none"> • Short chains (2-4 cells) • Capsule present, no spores • Smears from BAP and CHOC culture: <ul style="list-style-type: none"> • Long chains, no capsule • Spores in older cultures: oval, central to subterminal, no swelling of cell wall • Grows well on BAP and CHOC • No growth on MAC and EMB • Ground-glass colonies, 2-5 mm on BAP and CHOC at 24h • Aerobic growth as early as 4-8h • Flat or slightly convex with irregular edges that may have comma-like projections • Non-hemolytic on BAP • Tenacious, sticky colonies, adheres to agar surface • Catalase positive • Non-motile 	 <p>BRUCELLOSIS <i>Brucella</i> spp.</p> <ul style="list-style-type: none"> • Tiny, faintly staining, non-clustered, Gram negative coccobacilli (0.4 µm-0.8 µm) • Pinpoint colonies at 24h, and 0.5-1.0 mm after 48h • Non-hemolytic • Non-mucoid • Aerobic growth on BAP and CHOC (O₂ may be required by some strains) • No growth on MAC or EMB • Catalase, oxidase, urea; positive (Oxidase may be variable) • X and V factor (satellite test) negative (not required) • Non-motile (although motility testing not recommended for suspect <i>Brucella</i> spp.) 	 <p>GLANDERS <i>Burkholderia mallei</i></p> <ul style="list-style-type: none"> • Small straight, or slightly curved with rounded ends, Gram negative coccobacilli (1.5 µm-3 µm x 0.5-1.0 µm) • Cells arranged in pairs, parallel bundles, or Chinese letter form • Aerobic • Non-hemolytic • No growth or pinpoint on MAC at 48h • Catalase positive • Oxidase variable • Spot indole negative • Non-motile • No growth at 42 °C • Polymyxin B and colistin no zone • Penicillin resistant • Amoxicillin-clavulanate susceptible 	 <p>MELIOIDOSIS <i>Burkholderia pseudomallei</i></p> <ul style="list-style-type: none"> • Straight, or slightly curved Gram negative rod (2.0-5.0 µm x 0.4-0.8 µm) • Colonies may demonstrate bipolar morphology in direct specimens and peripheral staining in older cultures, which can mimic endospores • Aerobic • Non-hemolytic • Growth on MAC (may uptake pink dye) • Distinctive musty earthy odor, which is diagnostic (the odor is apparent without sniffing) • Oxidase positive • Spot indole negative • Motile • Growth at 42 °C • Polymyxin B and colistin no zone • Penicillin resistant • Amoxicillin-clavulanate susceptible 	 <p>TULAREMIA <i>Francisella tularensis</i></p> <ul style="list-style-type: none"> • Tiny, Gram negative coccobacilli (0.2-0.5 µm x 0.7-1.0 µm) • Poor counterstaining with safranin (basic fuchsin counterstain may increase resolution) • Pleomorphic • Mostly single cells • Aerobic, fastidious • No growth on MAC/EMB • Scarcely or no growth on BAP; may grow on primary culture, not well on subculture • Slow growing on CHOC, TM or BCYE: 1-2 mm after 48h • Colonies are opaque, grey-white, butyrous, smooth and shiny • Oxidase negative • Catalase negative or weakly positive • Satellite negative • Beta-lactamase positive 	 <p>PLAGUE <i>Yersinia pestis</i></p> <ul style="list-style-type: none"> • Plump, Gram negative rods (0.5 x 1.2 µm) seen mostly as single cells or pairs, and may demonstrate short chains in liquid media • May exhibit bipolar, "safety-pin" appearance in Giemsa stain or Wright's stain • Facultative anaerobe • Slow growing at 35 °C, better growth at 25-28 °C • Grey-white, translucent pinpoint colonies at 24h, usually too small to be seen, little to no hemolysis on BAP • At 48h, lactose non-fermenter on MAC or EMB • Catalase positive • Oxidase, urease (at 35 °C) and indole negative
---	---	---	---	---	--

FOLLOW ALL LABORATORY AND BIOSAFETY PROCEDURES TO RECOGNIZE AGENTS OF BIOTERRORISM
YOU ARE THE FIRST LINE OF DEFENSE — REFER TO CURRENT ASM SENTINEL LAB PROTOCOLS

Resources



Connect with APHL

APHL Blog



LAB Culture (podcast)



Lab Matters



Attend our conferences!



Connect with APHL on X, Facebook, LinkedIn, Instagram and ColLABorate Communities of Practice

2025 National APHL Conferences



ID Lab Con

Pasadena, California
March 25 – 27, 2025



APHL 2025 Annual Conference

Portland, Oregon
May 5 – 8, 2025



14th National Conference on Laboratory Aspects of Tuberculosis

Atlanta, Georgia
June 3–4, 2025



2025 APHL Newborn Screening Symposium

Providence, Rhode Island
October 5 – 9, 2025



Advancing HIV, STI and Viral Hepatitis Conference

Atlanta, Georgia
November 3–7, 2025



Contact:
chris.mangal@aphl.org

**Thank
You!**



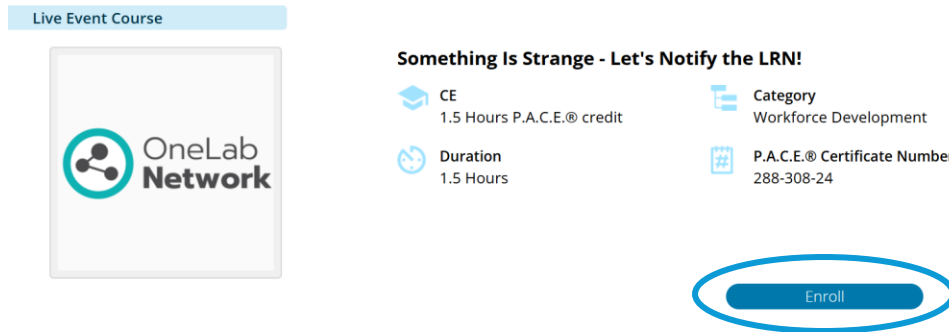


Questions?

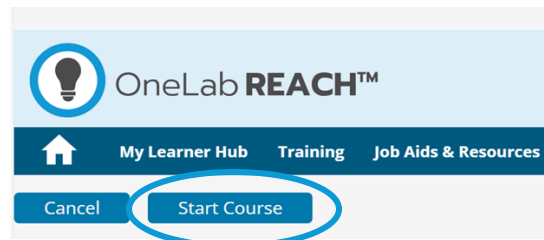


After participating in today's session, to receive continuing education credits you must:

1. Log into your [OneLab REACH account](#). You must be logged into your REACH account to access the evaluation.
2. Click on [this link](#) to take you to the survey.
3. Enter passcode "1HP3"
4. Click "Enroll"



5. Select "Start Course".



6. Select "Start".

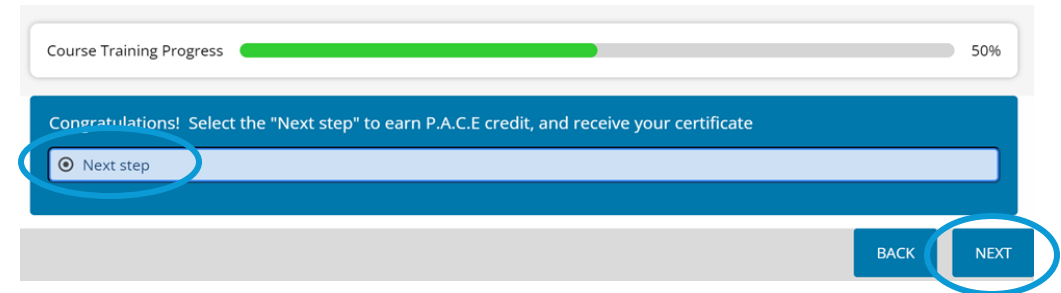


Something Is Strange - Let's Notify the LRN!

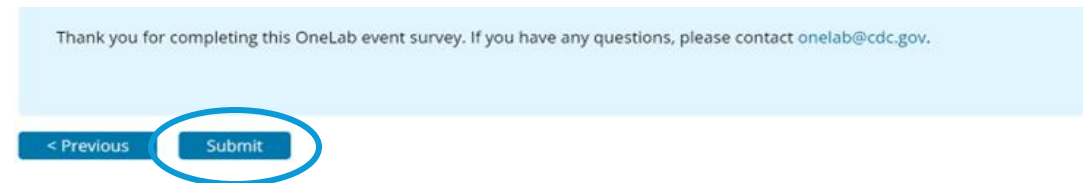
CE 1.5 Hours P.A.C.E.® credit	Category Workforce Development
Duration 1.5 Hours	P.A.C.E.® Certificate Number 288-308-24



7. Select "Next step" and "Next".



8. Complete the evaluation and click "Submit". Receive your P.A.C.E.® certificate in your [MyLearnerHub](#).



Upcoming Event!

Securing the Future: Exploring the Importance of Biosecurity

January 29, 2025, 12:00 p.m. – 1:00 p.m. ET

Additional details coming soon!

[**Register Now!**](#)



OneLab **Assessments**

Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov